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The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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Abstract

Objectives

To assess the effect on needed nursing time for dressing change.

Design, Setting, Participants

A parallel-group, open-label, randomized controlled trial in patients who are in need for a Peripherally Inserted Central Catheter insertion in one teaching hospital in Belgium. The follow lasted 180 days or until catheter removal, whatever came first. A computer generated table was used to allocate devices. Randomized patients were 105 adults (StatLock® n=53; SecurAcath® n=52) and primary analysis was based on all patients (n=92) with time measurements (StatLock® n=43; SecurAcath® n=49).

Interventions

StatLock® which has to be changed weekly versus SecurAcath® which could remain in place for the complete catheter dwell time.

Main outcome measure

Needed time for the dressing change at each dressing change (SecurAcath®) or at each dressing change combined with the change of the securement device (StatLock®).

Results

Median time needed for dressing change was 7.3 minutes (95% CI 6.4 minutes–8.3 minutes) in the StatLock® group and in the SecurAcath® group 4.3 minutes (95% CI 3.8 minutes-4.9 minutes) (P<0.0001). The time in the SecurAcath® group was reduced with 41% (95% CI:29%- 51%). Incidence rates of migration, dislodgement and catheter-related bloodstream infection were comparable across groups. Pain scores were higher with SecurAcath® than with StatLock® at insertion (P=0.02) and at removal (P<0.001), and comparable during dressing change (P=0.38) and during dwell time (P=0.995). The user-friendliness at insertion and removal was scored significantly higher for StatLock® than for SecurAcath® (P<0.05), except for the statement regarding to use the device routinely, at removal where no difference was found between the two devices (P=0.32).

Conclusion

Use of SecurAcath® saves time during dressing change compared to StatLock®. Training on correct placement and removal of SecurAcath® is critical to minimize pain.

Trial registration

NCT02311127

Strengths and limitations of this study

- Nursing procedural time as primary outcome measurement which is key when staff nurses are involved in device care on a regularly basis.

- Multiprofessional conducted trial which evaluated needed time for care, clinical outcomes and also usability data from device inserters, device users and patients.

- First randomised controlled trial with Securacath® versus StatLock® with rigorous trial methodology to enhance reliability of results despite securement devices are not amenable to blinding.

- Full economic assessment of the use of both securement devices is lacking.

Introduction

Peripherally inserted central catheters (PICCs) are mainly used for the administration of intravenous fluids, drugs and for blood sampling. PICCs may remain in place for months and therefore may be considered mid to long-term central venous access devices. However, PICCs tend to be non-cuffed and thus at higher risk of movement, migration and total dislodgement. Consequences related to these complications include bacterial migration and catheter-related bloodstream infection, venous thrombosis, treatment delay and catheter replacement.[1] Therefore adequate securement is critical during the complete PICC dwell time. Several securement and dressing products are available.[2] However, catheters with securement systems that need to be regularly changed might be prone to dislodgement because the catheter is free-floating during securement device changes. Moreover, these adhesive-based devices may lead to medical adhesive-related skin injury (MARSI).[3] A subcutaneous catheter securement system could overcome these two disadvantages: by not requiring removal until the end of treatment and not requiring adhesive securement to skin. In addition, unlike the adhesive securement device, the subcutaneous device does not need changing, therefore the time needed for the exit site care will be shortened. Declining hospital reimbursement and nursing shortages reduces the time available for bedside nurses to complete care activities.[4] Therefore new technologies should be critically evaluated for their added value in patient care and also their impact on nursing care activities. We conducted a randomized controlled trial to compare an adhesive-backed anchor pad with a subcutaneous catheter securement system for PICCs. The objective of this study was to determine differences in nursing time for dressing change. We also investigated complications and, experiences of the healthcare worker and the patient with the securement device at PICC insertion, during dressing change and at PICC removal.

Materials and methods

Study design

This investigator-driven study is a single-centre, parallel-group, open-label, randomized controlled trial. The study protocol was approved by hospitals local Ethics Committee (S57358), and the trial was registered at clinicaltrials.gov (NCT02311127). Patients were recruited in the university

hospitals Leuven, Belgium, where a team of interventional radiologists insert approximately 1000 PICCs per year. Advanced Practice Nurses from the vascular access team are responsible for development of procedures, staff education, research and troubleshooting in case of PICC-related problems. Patients were recruited between April 2015 and August 2015. Follow-up lasted until December 2015. Eligible patients were over 18 years old and scheduled for a PICC insertion with a polyurethane catheter, had a planned follow-up in the study centre and were able to speak and understand Dutch. Patients were excluded if they were unable to sign an informed consent form (ICF) and if they had a known allergy to nickel and/or ethylene oxide. Written informed consent was obtained before PICC insertion.

Outcomes and procedures

Our primary outcome measure was the time needed for the dressing change. We chose this endpoint because we hypothesized that the procedural time will be reduced if there is no need for a change of the securement device during dressing change. Moreover, we anticipated that the reduction in stress experienced by the nurse due to decreased risk of catheter dislodgement, would also contribute to decrease the time taken to change the dressing. Ward nurses measured the time taken for the dressing change at each dressing change (SecurAcath® group) or at each dressing change combined with the change of the securement device (StatLock® group). They used the clock in the patient room or a watch on a cell phone. The time was recorded in minutes starting from the moment that all material was prepared just before the removal of the catheter dressing till the end of the procedure with the application of the new catheter dressing.

We selected the following assessments as secondary outcomes: (1) catheter migration at dressing change, (2) catheter dislodgement resulting in premature PICC removal, (3) catheter-related bloodstream infection (CRBSI), (4) patient's pain and (5) usability of the securement devices.

Radiologists inserted single lumen Bard PowerPICCs (C.R. Bard Inc., Salt Lake, UT, USA) and they completed a case report form containing the indication for insertion, PICC details and perioperative problems. The experience of the radiologists who placed and, nurses and

physicians who removed the securement device, was assessed on a categorical level (no experience, < 10 and ≥ 10 times). The usability of the securement device was evaluated at PICC insertion and a second time at removal by scoring 4 statements (self-developed, close-ended statements with a 5 item Likert-type scale). Patients were asked if they had previously had a PICC inserted and which securement device was used.

Patients reported pain on a Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst pain possible) at securement placement, at each dressing change, at removal for the evaluation of the removal procedure and also the complete catheter dwell time.

At dressing change, nurses described their own level of experience with the specific securement device (no experience, < 10 handlings and ≥ 10 handlings). At every dressing change, the external catheter length was measured to document eventual catheter migration. The external length was defined as zero when the zero mark sign of the first bullet marked on the PICC was at exit site for the StatLock® for the SecurAcath®, if the zero mark sign was visible just behind the SecurAcath® device, or in other words 3 cm from the exit site. Migration was defined as an accidental partial slip out of the PICC with an external catheter length of ≥ 3 cm from the zero mark, while the PICC could be used further.

At PICC removal, the reason for removal was recorded. Catheter dislodgement was defined as the accidental partial or total catheter slip out resulting in loss of the PICC. CRBSI was studied retrospectively by reviewing all microbial cultures available in the hospital information system. We defined laboratory-confirmed CRBSI as the presence of positive blood cultures from both the PICC and peripheral veins with the same pathogen and fever or chills in the absence of other infection sources.[5] Furthermore, specific removal data were collected: complications during removal if any, and, in the SecurAcath® group, the use of any local anaesthesia and technique of removal (cutting the device before removal or not). Patients reported whether they would choose the same type of securement device if needed in the future (yes/no). All data were recorded on specially designed forms. Patients were followed for a maximum of 180 days or until catheter removal, whatever came first.

Calculation of the sample size

We expected less time for dressing change in the SecurAcath® group compared to the StatLock® group. We presumed, based on our observations, a time reduction of 30% for the dressing change in the SecurAcath® group due to the omission of the time spent to remove and to apply a new Statlock®. Based on a two-sided two-sample pooled t-test of a mean ratio with lognormal data, 102 subjects in total were needed to have 80% power (with α set at 5%) to detect a 30% reduction in time needed, assuming a coefficient of variation (ratio of standard deviation versus the mean) equal to 0.7. The sample size calculation was performed under the worst case scenario that only a single measurement would be available per patient.

Randomization and masking

We randomly assigned patients in a 1:1 ratio following a simple randomization procedure (computerized random numbers) to 2 groups: the StatLock® adhesive device (C.R.Bard Inc., Salt Lake, UT, USA) or the SecurAcath® subcutaneous device (Interrad Medical, Plymouth, Minnesota, USA). In the StatLock® group, the securement device together with the catheter dressing, was changed weekly or earlier if loose, wet or soiled. In the SecurAcath® group, the securement system remained in place for the complete catheter dwell time while the catheter dressing was changed weekly or earlier if loose, wet or soiled. The allocation sequence was concealed from researchers who enrolled patients according to sequentially numbered opaque sealed envelopes which contained a card with the group assignment. Neither patients nor assessors could be blinded because the device was externally visible.

Statistical analysis

A linear mixed model with a random subject effect to handle the multiple observations per subject was used to compare the time needed for the dressing change between both groups. The analysis was performed on log-transformed time values. In both groups, geometric means, their ratio and 95% confidence intervals (CI) that are obtained after backtransforming to the original scale, are reported. All patients with measurements were included in the analysis. Analysis is carried out using the SAS software, version 9.2 (SAS Institute, Inc., Cary, NC). Secondary

outcomes are analysed using SPSS® version 19, (IBM® Statistics SPSS Inc, Chicago, IL). The following agreement levels on the statements about the securement device for the Likert scores are used: 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree. Results of the NRS pain scores are categorized to none (0), mild (1-2-3), moderate (4-5-6) and severe (7-8-9-10). Nominal and ordinal data were expressed in absolute numbers and percentages, and continuous data were expressed in mean and standard deviation (medians and quartiles when required). Comparisons of ordinal variables were performed by Mann-Whitney U-test and a Mann-Whitney U test correcting for clustering (since multiple scores per subject can be available) was used to calculate differences in pain scores during dressing changes between the two groups.[6] The Chi-square or Fisher's exact test was used to compare proportions. All tests were two-sided and P-values smaller than 0.05 were considered significant.

Results

Patient and device characteristics

We assessed 341 patients for eligibility; 105 met the inclusion criteria. After randomization, 53 patients were allocated to receive a StatLock® and 52 a SecurAcath® (Figure 1). The 2 groups were comparable in terms of patient and PICC characteristics (Table 1). The most frequent indication for PICC insertion was the administration of intravenous antibiotic therapy. Patients were followed for a total of 3113 days. The median number of catheter days was 16 days (Q1 = 10 days; Q3 = 38 days) in the StatLock® group and 21 days (Q1 = 11days; Q3 = 41 days) in the SecurAcath® group. At least one PICC had previously been inserted in 16 patients (31.4%) in the StatLock® group and in 17 patients (33.3%) in the SecurAcath® group. Of these, 1 patient in the SecurAcath® group and 3 patients in the StatLock® group confirmed that they have had the PICC secured with a SecurAcath® in the past. At insertion, most radiologists had some experience with securement device placement and used it previously ≥ 10 times in 37 (88.1%) and in 31 (73.8%) cases in the StatLock® group and in the SecurAcath® group, respectively. No procedural complications were reported. In 22 of the 31 evaluations (71.0%) in the Statlock® group and 29 of

the 43 evaluations (67.3%) in the SecurAcath® group, healthcare workers who removed the PICC with securement device were experienced and removed the device already ≥ 10 times.

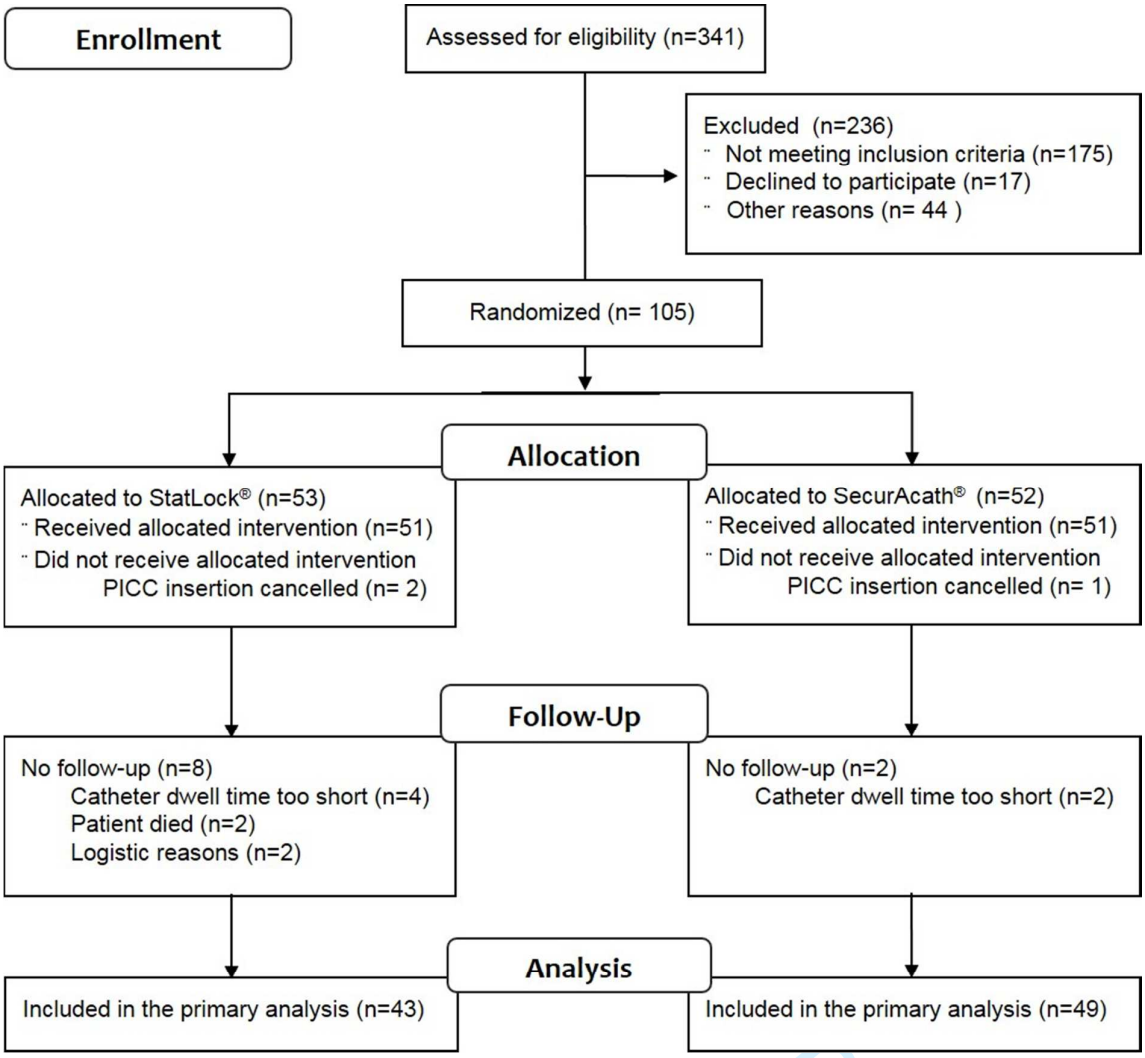

Figure 1 Flow diagram

Table 1 Patient and PICC characteristics, and healthcare worker's level of experience with the securement device

	StatLock® (n=53)	SecurAcath® (n=52)
Sex		
Females n (%)	29 (54.7)	21 (40.4)
Median age in years (Q1 – Q3)	62 (51 – 69)	64 (50 – 71)
Reason for PICC insertion	n (%)	n (%)
Antibiotic therapy	26 (49.1)	26 (50.0)
Supportive care	18 (34.0)	13 (25.0)
Chemotherapy	9 (17.0)	11 (21.2)
Other	0 (0.0)	2 (3.8)
Single lumen PICC diameter	n (%)	n (%)
4 FR	49 (92.5)	46 (88.5)
5 FR	2 (3.8)	5 (9.6)
Insertion cancelled	2 (3.8)	1 (1.9)
External length in cm at insertion	n = 51	n = 50
Mean (SD)	0.1 (0.6)	0.5 (0.9)
Min - max	-1 – 2	0 – 2
Number of catheter days	n = 51	n = 51
Total number	1541	1572
Median (Q1 – Q3)	16 (10 – 38)	21 (11 – 41)
Min - max	1 – 179	1 – 180
Radiologist's experience with securement device at insertion	n = 42 n (%)	n = 42 n (%)
First time user	1 (2.4)	4 (9.5)
< 10 times	4 (9.5)	7 (16.7)
≥ 10 times	37 (88.1)	31 (73.8)
Nurse's experience with securement device at dressing change	n = 156 n (%)	n = 159 n (%)
No experience	23 (14.7)	67 (42.2)
< 10 times	59 (37.8)	69 (43.4)
≥ 10 times	74 (47.4)	23 (14.5)
Experience with securement device at removal	n = 31 n (%)	n = 43 n (%)
First time user	2 (6.5)	7 (16.3)
< 10 times	7 (22.6)	7 (16.3)
≥ 10 times	22 (71)	29 (67.4)

Time needed for dressing change

Time was measured during 325 dressing changes with 161 in the StatLock® group and 164 in the SecurAcath® group with a mean numer of 3.74 (SD 3.48) and 3.35 (SD 2.89) measurements per patient, respectively. The maximum number of time measurements per patient was 21 in the StatLock® group and 16 in the SecurAcath® group.

In the StatLock® group, the time needed for dressing change (Statlock® change included) was 7.3 minutes (95% CI 6.4 – 8.3) and in the SecurAcath® group 4.3 minutes (95% CI 3.8 – 4.9) (P <0.001). The time in the SecurAcath® group was reduced with 41% (95% CI:29% - 51%).

Migration, dislodgement, infection, pain and usability of device placement and removal

Table 2 summarizes the secondary outcomes. Nurses assessed catheter migration at each dressing change. They reported 2 cases of an external catheter part of ≥3 cm: 4 cm (n=1) in the StatLock® group versus 20 cm (n=1) in the SecurAcath® group (P= 1.00).

Dislodgement resulted in accidental PICC removal in 2 PICCs (1.3/1000 catheter days) in the StatLock® and 3 PICCs (1.9/1000 catheter days) in the SecurAcath® group (P= 1.00).

Lab-confirmed CRBSI occurred in 2 cases (1.3/1000 catheter days) in the StatLock® group versus 1 case (0.6/1000 catheter days) in the SecurAcath® group (P=1.00).

We found statistically significant differences between pain scores in the StatLock® versus SecurAcath® group at insertion (P=0.02) and at removal (P< 0.001) but not for the total dwell time (P=0.99) nor for pain scores during dressing change (P= 0.29). We found a statistically significant difference in favour of StatLock® regarding the usability at insertion and removal, except for the recommendation at removal to use the device systematically. At insertion, radiologists agreed to strongly agreed that the StatLock® was user-friendly (mean score 4.5) and was without difficulties to place (mean score 4.5), while the SecurAcath® was rated more neutrally regarding user-friendliness (mean score 3.4) and regarding difficulties when placing the device (mean score 3.6). Inserters agreed also that they would prefer (mean score 4.0) and would recommend (mean score 3.9) StatLock® for PICC securement. Inserters were neutral regarding the preference of SecurAcath® (mean score 3.1), and whether they would recommend (mean score 3.0) it when inserting PICCs. Nurses and physicians who removed the PICCs agreed with the statement that the StatLock® is user-friendly (mean score 4.3) and may be removed without difficulties (mean score 4.7). Healthcare workers tended to agree that SecurAcath® is user-friendly (mean score 3.6) and may be removed without difficulties (mean score 3.7). They were neutral in the preference (mean score 3.1) and the recommendation (mean score 3.3) of StatLock® and tended to agree to prefer (mean score 3.6) and recommend (mean score 3.6) SecurAcath®.

Table 2 Secondary outcomes

	StatLock®	SecurAcath®	Effect Size	P
			OR (95% CI)	
Migration (≥3 cm) reported during dressing change	1/161 (0.6%)	1/164 ((0.6%)	0.98 (0.06 – 15.83)	1.00
Dislodgement resulting in PICC removal	2/51 (3.9%)	3/51 (5.9%)	1.53 (0.25 – 9.57)	1.00
Confirmed CRBSI at PICC removal	2/51 (3.9%)	1/51 (2.0%)	0.49 (0.04 – 5.58)	1.00
			AUC (95% CI)	
Pain at insertion	n = 47	n = 49	0.58 (0.47 – 0.70)	0.02
None (NRS = 0)	44 (93.6%)	38 (77.6%)		
Mild (NRS = 1– 2 – 3)	3 (6.4%)	8 (16.3%)		
Moderate (NRS = 4 – 5 – 6)	0	2 (4.1%)		
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.1%)		
Pain (highest reported score) during dressing change	n = 43	n = 48	0.56 (0.44 – 0.68)	0.29
None (NRS = 0)	16 (37.2%)	20 (41.7%)		
Mild (NRS = 1– 2 – 3)	22 (51.2%)	11(22.9%)		
Moderate (NRS = 4 – 5 – 6)	5 (11.6%)	12 (25.0%)		
Severe (NRS = 7 – 8 – 9 – 10)	0	5 (10.4%)		
Pain during dwell time	n = 31	n = 42	0.51 (0.38 – 0.65)	0.995
None (NRS = 0)	19 (61.3%)	28 (66.7%)		
Mild (NRS = 1– 2 – 3)	12 (38.7%)	11 (26.2%)		
Moderate (NRS = 4 – 5 – 6)	0	2 (4.8%)		
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.4%)		
Pain at removal	n = 25	n = 41	0.71 (0.60 – 0.84)	<0.001
None (NRS = 0)	19 (76.0%)	17(41.5%)		
Mild (NRS = 1– 2 – 3)	6 (24.0%)	10 (24.4%)		
Moderate (NRS = 4 – 5 – 6)	0	11 (26.8%)		
Severe (NRS = 7 – 8 – 9 – 10)	0	3 (7.3%)		
Corresponding score for evaluation of the device at insertion*	n = 47	n = 50		
I find the device user-friendly to place				
Mean (SD)	4.5 (0.6)	3.4 (1.0)	0.79 (0.71 – 0.88)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	3.0 (3.0 – 4.0)		
I have no difficulties to place the device				
Mean (SD)	4.5 (0.6)	3.6 (0.9)	0.76 (0.67 – 0.86)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)		
I prefer this device type				
Mean (SD)	4.0 (0.9)	3.1 (0.8)	0.77 (0.67 – 0.86)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)		
I recommend this device type to use systematically				
Mean (SD)	3.9 (0.8)	3.0 (0.6)	0.79 (0.70 – 0.88)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)		
Corresponding score for evaluation of the device at removal*	n = 32	n = 44		
I find the device user-friendly to remove				
Mean (SD)	4.3 (0.7)	3.6 (1.0)	0.74 (0.62 – 0.85)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)		
I have no difficulties to remove the device				
Mean (SD)	4.7 (0.7)	3.7 (1.0)	0.80 (0.70 – 0.90)	<0.001
Median (Q1-Q3)	5.0 (5.0 – 5.0)	4.0 (3.0 - 4.0)		
I prefer this device type				
Mean (SD)	3.1 (0.7)	3.6 (0.9)	0.67 (0.55 – 0.79)	0.004
Median (Q1-Q3)	3.0 (3.0 – 3.0)	3.0 (3.0 – 4.0)		
I recommend this device type to use systematically				
Mean (SD)	3.3 (0.9)	3.6 (0.9)	0.56 (0.43 – 0.69)	0.32
Median (Q1-Q3)	3.0 (3.0 – 4.0)	3.0 (3.0 – 4.0)		

* 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree; OR: Odds Ratio for SecurAcath® versus StatLock®; AUC (area under the curve): discriminative ability 0.5 equals random prediction, 1 equals perfect discrimination; nominal variables are analysed using a Fishers Exact test, and ordinal variables using a Mann-Whitney U test.

Problems during dressing change and end of study reasons

Table 3 summarizes the complications reported during dressing change. No complications were found during dressing changes in 61.5% in the StatLock® group and in 65,9% in the SecurAcath® group. Both groups were comparable regarding complications (P=0.41). Pain without any other complication was explicitly mentioned in 9.9 % and 10.4% of patients in the StatLock® group and SecurAcath® group, respectively (P=0.90). In one patient in the StatLock® group, leakage via exit site, with or without reporting of a loose dressing, was reported during 5 dressing changes.

	StatLock® n = 161 n (%)	SecurAcath® n = 164 n (%)	Odds Ratio (95% CI)	P
None	99 (61.5)	108 (65.9)	1.21 (0.77 – 1.90)	0.41
Bleeding/oozing/haematoma	21 (13.0)	24 (14.6)	1.14 (0.61 – 2.15)	0.68
Pain at exit site	16 (9.9)	17 (10.4)	1.05 (0.51 – 2.15)	0.90
Signs of exit site infection	10 (6.2)	7 (4.3)	0.67 (0.25 – 1.81)	0.43
Medical Adhesive-related Skin Injuries	6 (3.7)	7 (4.3)	1.15 (0.38 – 3.51)	0.80
Migration (≥3 cm)	1 (0.6)	1 (0.6)	0.98 (0.06 – 15.83)	1.00
Leakage and loose dressing	5 (3.1)	0	nd (0.00 – 1.06)	0.03
Other	3 (1.9)	0	nd (0.00 – 2.37)	0.12

Table 3 Problems during dressing change

Odds Ratio for SecurAcath® versus StatLock® without taken clustering into account; nd= not determined; P-values from Chi Square or Fishers Exact tests

The reasons for the end of study were listed in table 4. PICCs were prematurely removed due to complications in 19.6% of cases (n=10) in the StatLock® group and in 21.6% of cases (n=11) in the SecurAcath® group.

	StatLock® n = 51	SecurAcath® n = 51	Odds Ratio (95% CI)	P
End of IV therapy	31 (60.8%)	35 (68.6%)	1.41 (0.62 – 3.19)	0.41
Patient deceased	4 (7.8%)	4 (7.8%)	1.00 (0.24 – 4.24)	1.00
End of study time period	0	1 (2.0%)	nd (0.03 – +inf)	1.00
Elective exchange for tunnelled catheter	1 (2.0%)	0	nd (0.00 – 39)	1.00
Patient's choice to terminate study	1 (2.0%)	0	nd (0.00 – 39)	1.00
Complications				
Confirmed CRBSI	2 (3.9%)	1 (2.0%)	0.49 (0.04 – 5.58)	1.00
Suspected CRBSI	3 (5.9%)	6 (11.8%)	2.13 (0.50 – 9.04)	0.49
Dislodgement	2 (3.9%)	3 (5.9%)	1.53 (0.25 – 9.57)	1.00
Malfunction	3 (5.9%)	1 (2.0%)	0.32 (0.03 – 3.18)	0.62
Unknown	4 (7.8%)	0	nd (0.00 – 1.48)	0.24

Table 4 Reason for end of study

Odds Ratio for SecurAcath® versus StatLock®; nd= not determined; inf=infinity= ∞; P-values from Chi Square or Fishers Exact test

Difficulties in removing the SecurAcath® were reported in 15 cases. A local anaesthetic with lidocaine (Linisol 2%) was used 7 times for the following reasons: difficult removal (n=4), removal one day after insertion (n=1), removal after several attempts by an inexperienced nurse (n=1), and unknown (n=1). In 71.8% of cases (n=28), the SecurAcath® was cut in two just before removal.

Patients stated to choose for the same securement device in 88.5% (n=23) and 82.5% (n=33) of cases in the StatLock® and in the SecurAcath® group, respectively. The following reasons for disapproval were given in the StatLock® group: too frequent device changes (n=1) and MARSI (n=1), and in the SecurAcath® group: too painful (n=4) and causing a feeling of a burden (n=1).

Discussion

This study was based on the assertion that the change of the StatLock® device is a time-consuming and potentially risky procedure creating stress for patients and nurses. Therefore we

wanted to test the hypothesis that the time for dressing change is reduced when using a securement device that does not need changing during weekly exit site care. Indeed, we found that time for the weekly dressing change was statistically significantly lower in the SecurAcath® group than in the StatLock® group.

The ultimate goal of a securement device is: (1) to secure the catheter to prevent catheter migration and dislodgement (2) to add no CRBSI risk, (3) to be painless and (4) to be user-friendly to handle. First, catheter migration was reported at dressing change once in both groups. In the SecurAcath® group, the migration of 20 cm could be attributed to an incomplete closing of the SecurAcath® lid. Although we found 6 more migration reports, 4 patients in the SecurAcath® group (3 cm (n=3) and 13 cm (n=1) and 2 patients in the StatLock® group (once 3cm and once10 cm), we assume an incorrect measurement in all these cases. Indeed, the following external catheter length report at dressing change in the same patients didn't report any migration anymore. Moreover, in the 13 cm-migration case an chest X-Ray confirmed correct tip placement.

Second, prevention of accidental catheter dislodgement is a real clinical challenge. In our study, 3 in 5 patients with catheter dislodgement were disorientated, the fourth patient reported that the incident occurred during the night. Finally, in the fifth patient, leakage (no blood) via the exit site loosened the catheter dressing and also the StatLock®. The 5.9% dislodgement with SecurAcath® is in line with the 7.4% of patients that removed their own catheter (n=4) or had a dislodged catheter (n=1) despite SecurAcath® securement in the study of Egan and colleagues.[7] However, the 4.6% of dislodgement we found with StatLock® is lower than the 6.1% - 12% in adults [1,8] and 30.8% in paediatrics [9] reported in other series.

Third, the incidence of confirmed CRBSI is low (0.6 per 1000 catheter days) for SecurAcath® compared to 1.5/1000 catheter days in a previous study with SecurAcath® .[7]

Fourth, we learned that pain is a concern when using SecurAcath®. We found higher pain scores with SecurAcath® than with StatLock® at insertion and removal. From our own pilot trial of 70 devices (unpublished data), we learned that at insertion, the SecurAcath® has to be placed deeply enough to avoid pain and that removal requires a certain force and dexterity. In our current study, none of the SecurAcath® devices required premature removal due to pain. Nonetheless, a local anaesthetic is always used at PICC insertion and could also be considered

too at removal of a SecurAcath® .[10] We found a mean NRS score of 1.0 ±1.8 for SecurAcath® during PICC dwell time which is comparable with the 0.7± 1.6 as previously reported.[7] The mean NRS score of 2.1 ± 2.5 at removal was slightly higher than the1.5 ± 2.5 reported in Egan's study.[7] However, patients reported the highest pain scores after dressing changes in both groups. It was clear from the free comments on the registration forms that patients, in both groups, included in their pain score the experienced pain during removal of the standard semi-permeable dressing.

Finally, we found that the SecurAcath® was considered statistically significantly less user-friendly than the StatLock®. Indeed, this could be explained by the learning curve for placement and removal of SecurAcath®. However, at removal, no difference was found between the two devices regarding the recommendation to use the device systematically. An explanation could be that nurses mostly removed the system. Potentially, they included the weekly change for StatLock® and the more difficult removal of SecurAcath® when scoring the recommendation to use the securement device systematically. So both systems have their advantages and disadvantages and at removal healthcare workers considered neither system ideal.

We conclude that the use of SecurAcath® is safe regarding migration, dislodgement and CRBSI, still, pain could be maximally avoided by training the users.

Our study has some methodological limitations. We included only 31% of eligible patients mainly because at the moment of PICC insertion, patients were unable to sign the ICF which might be explained by the setting of a tertiary care hospital. Though we presume no impact on our primary outcome, the needed time for dressing change, because we assume a difference in time if you need to change the securement device or not, independent of e.g. the patient's condition or the ability to speak Dutch. The analysis sample contained only 92 patients despite we randomized 105 patients. However, this was compensated by patients having multiple measurements while the sample size was calculated based on a minimum of one measurement. We also missed data at removal, especially in the StatLock® group, because these PICCs could be easily removed by staff nurses while in the SecurAcath® group, nurses of the vascular access team involved in the study removed most of the PICCs. However, we assume limited bias in the usability results because StatLock® is not associated with pain or difficulties at removal. Finally,

we did not perform a full economic assessment of the use of both devices. Nevertheless, the reduced needed nursing time for dressing change with StatLock® should be taken into account in further financial evaluations. Further research should focus on strategies to reduce pain associated with SecurAcath® and also with semi-permeable dressings. Additionally, the ease of SecurAcath® removal after a long dwell time should be further investigated because in our study, the dwell time was limited to 180 days.

SecurAcath® is a valuable and safe alternative for StatLock®. However, knowledge and training for precise placement, for smooth handling during dressing change and for a correct removal of the device, are critical.

Conclusion

We compared 2 devices for PICC securement, namely StatLock® which has to be changed weekly, and SecurAcath® which remains in place for the complete PICC dwell time. We found a statistically significant reduced time for the dressing change. In the development of new technologies, the potential of reducing nursing procedural time is an important factor given the nursing shortage.

Acknowledgement

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Contributorship statement

Hereby I confirm that all authors meet the criteria for authorship. They have approved the final article and that all those entitled to authorship are listed as authors. Please find more details for each author below.

G. A. Goossens: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

N. Grumiaux: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

C. Janssens: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

M. Jérôme : contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

S. Fieuws: contributions to conception and design, data analysis and interpretation, writing, final approval of the version to be published.

P. Moons: contributions to conception and design, data interpretation, writing, final approval of the version to be published.

M. Stas: contributions to data interpretation, writing, final approval of the version to be published.

G. Maleux: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published

Competing interests

All authors declared no conflicts of interest for this study.

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Data sharing statement

All available data can be obtained from the corresponding author.

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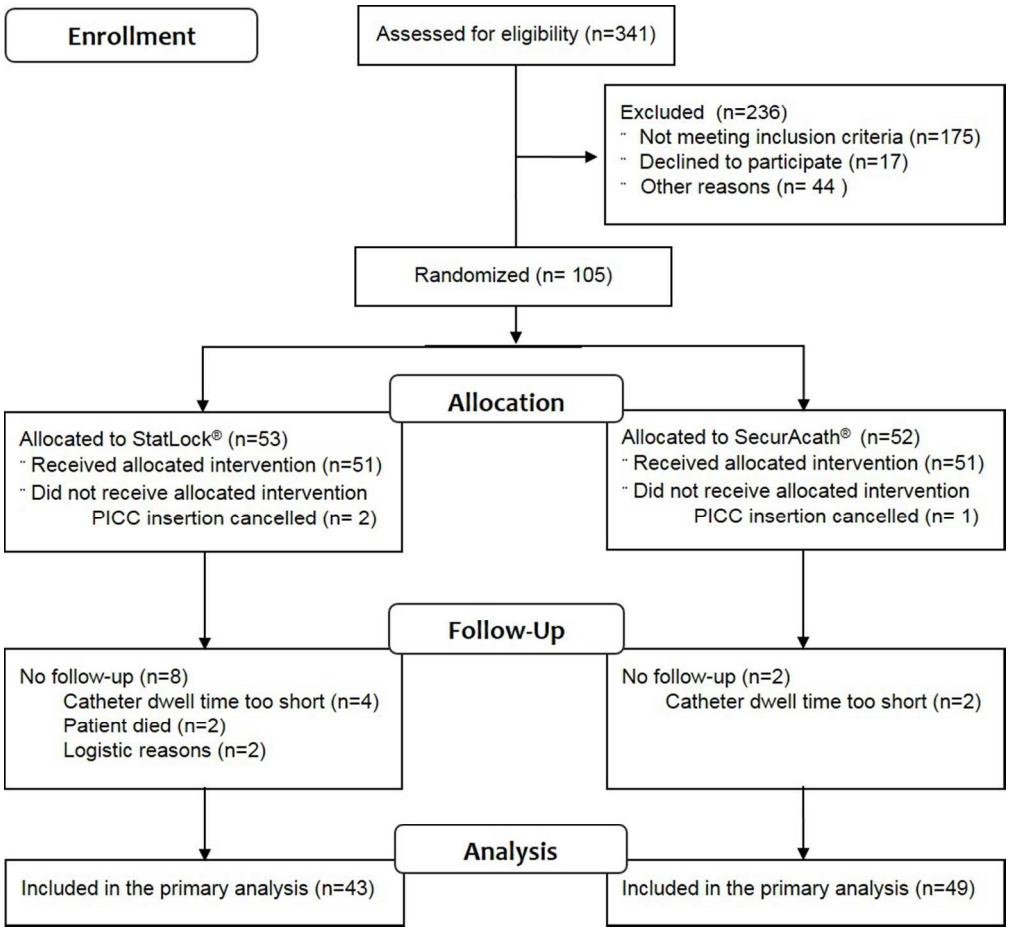
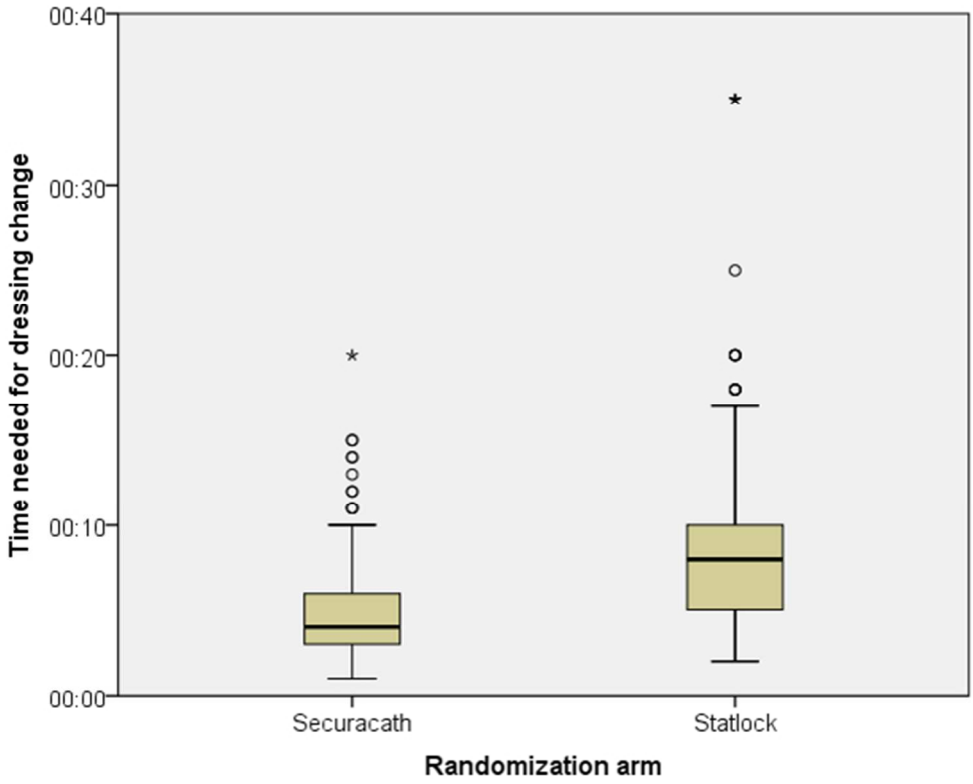


Figure 1 Flow diagram

171x157mm (150 x 150 DPI)



166x133mm (96 x 96 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NAP
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NAP
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NAP
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NAP
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NAP
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NAP
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-10 figure 1 flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NAP
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11 Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11-16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11-16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NAP
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NAP
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-19
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	Local EC
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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Abstract

Objectives

To assess the effect on needed nursing time for dressing change.

Design, Setting, Participants

A parallel-group, open-label, randomized controlled trial in patients who are in need for a Peripherally Inserted Central Catheter insertion in one teaching hospital in Belgium. The follow-up lasted 180 days or until catheter removal, whatever came first. A computer generated table was used to allocate devices. Randomized patients were 105 adults (StatLock® n=53; SecurAcath® n=52) and primary analysis was based on all patients (n=92) with time measurements (StatLock® n=43; SecurAcath® n=49).

Interventions

StatLock® which has to be changed weekly versus SecurAcath® which could remain in place for the complete catheter dwell time.

Main outcome measure

Needed time for the dressing change at each dressing change (SecurAcath®) or at each dressing change combined with the change of the securement device (StatLock®).

Results

Median time needed for dressing change was 7.3 minutes (95% CI 6.4 minutes–8.3 minutes) in the StatLock® group and in the SecurAcath® group 4.3 minutes (95% CI 3.8 minutes-4.9 minutes) (P<0.0001). The time in the SecurAcath® group was reduced with 41% (95% CI:29%- 51%). Incidence rates of migration, dislodgement and catheter-related bloodstream infection were comparable across groups. Pain scores were higher with SecurAcath® than with StatLock® at insertion (P=0.02) and at removal (P<0.001), and comparable during dressing change (P=0.38) and during dwell time (P=0.995). User-friendliness was scored at insertion and removal. All statements regarding the user-friendliness were scored significantly higher for StatLock® than for SecurAcath® (P<0.05). Only for the statement regarding the routine use of the device, which was asked at removal, no difference was found between the two devices (P=0.32).

Conclusion

Use of SecurAcath® saves time during dressing change compared to StatLock®. Training on correct placement and removal of SecurAcath® is critical to minimize pain.

Trial registration

NCT02311127

Strengths and limitations of this study

- Nursing procedural time as primary outcome measurement which is key when staff nurses are involved in device care on a regularly basis.

- Multi-professional conducted trial which evaluated needed time for care, clinical outcomes and also usability data from device inserters, device users and patients.

- First randomised controlled trial with Securacath® versus StatLock® with rigorous trial methodology to enhance reliability of results despite securement devices are not amenable to blinding.

- Full economic assessment of the use of both securement devices is lacking.

Introduction

Peripherally inserted central catheters (PICCs) are mainly used for the administration of intravenous fluids, drugs and for blood sampling. PICCs may remain in place for months and therefore may be considered mid to long-term central venous access devices. However, PICCs tend to be non-cuffed and thus at higher risk of movement, migration and total dislodgement. Consequences related to these complications include bacterial migration and catheter-related bloodstream infection, venous thrombosis, treatment delay and catheter replacement.[1] Therefore adequate securement is critical during the complete PICC dwell time. Several securement and dressing products are available.[2] However, catheters with securement systems that need to be regularly changed might be prone to dislodgement because the catheter is free-floating during securement device changes. Moreover, these adhesive-based devices may lead to medical adhesive-related skin injury (MARSI).[3] A subcutaneous catheter securement system could overcome these two disadvantages: by not requiring removal until the end of treatment and not requiring adhesive securement to skin. In addition, unlike the adhesive securement device, the subcutaneous device does not need changing, therefore the time needed for the exit site care will be shortened. Declining hospital reimbursement and nursing shortages reduces the time available for bedside nurses to complete care activities.[4] Therefore new technologies should be critically evaluated for their added value in patient care and also their impact on nursing care activities. We conducted a randomized controlled trial to compare an adhesive-backed anchor pad with a subcutaneous catheter securement system for PICCs. The objective of this study was to determine differences in nursing time for dressing change. We also investigated complications and, experiences of the healthcare worker and the patient with the securement device at PICC insertion, during dressing change and at PICC removal.

Materials and methods

Study design

This investigator-driven study is a single-centre, parallel-group, and open-label, randomized controlled trial (RCT). The study protocol was approved by hospitals local Ethics Committee (S57358), and the trial was registered at clinicaltrials.gov (NCT02311127). Patients were

recruited in the university hospitals Leuven, Belgium, where a team of interventional radiologists insert approximately 1000 PICCs per year. Advanced Practice Nurses (APN) from the vascular access team are responsible for development of procedures, staff education, research and troubleshooting in case of PICC-related problems. Patients were recruited between April 2015 and August 2015. Follow-up lasted until December 2015. Eligible patients were over 18 years old and scheduled for a PICC insertion with a polyurethane catheter, had a planned follow-up in the study centre and were able to speak and understand Dutch. Patients were excluded if they were unable to sign an informed consent form (ICF) and if they had a known allergy to nickel and/or ethylene oxide. All patients scheduled for PICC insertion in the IR suite were screened by a member of the research team for eligibility. Patients were recruited by the same team at a hospital ward or in rare occasions in the waiting room of the IR suite. Written informed consent was obtained before PICC insertion.

Outcomes and procedures

Our primary outcome measure was the time needed for the dressing change. We chose this endpoint because we hypothesized that the procedural time will be reduced if there is no need for a change of the securement device during dressing change. Moreover, we anticipated that the reduction in stress experienced by the nurse due to decreased risk of catheter dislodgement, would also contribute to decrease the time taken to change the dressing. Ward nurses measured the time taken for the dressing change at each dressing change (SecurAcath® group) or at each dressing change combined with the change of the securement device (StatLock® group). They used the clock in the patient room or a watch on a cell phone. The time was recorded in minutes starting from the moment that all material was prepared just before the removal of the catheter dressing till the end of the procedure with the application of the new catheter dressing. In both groups similar types of catheter dressing were used. At insertion, a gauze dressing, (Cosmopor® E, Hartmann) which has to be changed within 24 hours, was applied thereafter a transparent semipermeable membrane (TSM) dressing (Tegaderm™ 3M) was used. The TSM dressing was always placed over the StatLock® (Figure 1) and SecurAcath® (Figure 2).

In case of signs of exit site infection, a Biopatch® (Johnson & Johnson) was applied. Cavilon™(3M) was used in case of skin irritation.

We selected the following assessments as secondary outcomes: (1) catheter migration at dressing change, (2) catheter dislodgement resulting in premature PICC removal, (3) catheter-related bloodstream infection (CRBSI), (4) patient's pain and (5) usability of the securement devices.

At the initiation of SecurAcath® in the hospital, 6 months before study start, inserters followed a formal training on the placement of SecurAcath® and also the APN of the vascular access team were trained for device removal. The first 70 patients with a PICC secured with SecurAcath® were followed closely to monitor problems and complications with the devices, including optimising placement and removal technique. These trained interventional radiologists inserted Bard PowerPICCs (C.R. Bard Inc., Salt Lake, UT, USA) and they completed a case report form containing the indication for insertion, PICC details and perioperative problems. The experience of the radiologists who placed and, nurses and physicians who removed the securement device, was assessed on a categorical level (no experience, < 10 and ≥ 10 times). APN from the vascular access team removed the SecurAcath®. The usability of the securement device was evaluated at PICC insertion and a second time at removal by scoring 4 statements (self-developed, close-ended statements with a 5 item Likert-type scale). Patients were asked if they had previously had a PICC inserted and which securement device was used.

Patients reported pain on a Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst pain possible) at securement placement, at each dressing change, at removal for the evaluation of the removal procedure and also the complete catheter dwell time.

At dressing change, nurses described their own level of experience with the specific securement device (no experience, < 10 handlings and ≥ 10 handlings). At every dressing change, the external catheter length was measured to document eventual catheter migration. The external length was defined as zero when the zero mark sign of the first bullet marked on the PICC was at exit site for the StatLock® for the SecurAcath®, if the zero mark sign was visible just behind the SecurAcath® device, or in other words 3 cm from the exit site. Migration was defined as an accidental partial slip out of the PICC with an external catheter length of ≥ 3 cm from the

zero mark, while the PICC could be used further. We opt to define migration as a 3 cm supplementary external movement of the catheter because this is a substantial slip out of the catheter which could lead to loss of venous access.

At PICC removal, the reason for removal was recorded. Catheter dislodgement was defined as the accidental partial or total catheter slip out resulting in loss of the PICC. CRBSI was studied retrospectively by reviewing all microbial cultures available in the hospital information system. We defined laboratory-confirmed CRBSI as the presence of positive blood cultures from both the PICC and peripheral veins with the same pathogen and fever or chills in the absence of other infection sources.[5] Furthermore, specific removal data were collected: complications during removal if any, and, in the SecurAcath® group, the use of any local anaesthesia and technique of removal (cutting the device before removal or not). Patients were asked whether they would choose the same type of securement device if needed in the future (yes/no). All data were recorded on specially designed forms. Patients were followed for a maximum of 180 days or until catheter removal, whatever came first.

Calculation of the sample size

We expected less time for dressing change in the SecurAcath® group compared to the StatLock® group. We presumed, based on our observations, a time reduction of 30% for the dressing change in the SecurAcath® group due to the omission of the time spent to remove and to apply a new Statlock®. Based on a two-sided two-sample pooled t-test of a mean ratio with lognormal data, 102 subjects in total were needed to have 80% power (with α set at 5%) to detect a 30% reduction in time needed, assuming a coefficient of variation (ratio of standard deviation versus the mean) equal to 0.7. The sample size calculation was performed under the worst case scenario that only a single measurement would be available per patient.

Randomization and masking

We randomly assigned patients in a 1:1 ratio following a simple randomization procedure (computerized random numbers) to 2 groups: the StatLock® adhesive device (C.R.Bard Inc., Salt Lake, UT, USA) or the SecurAcath® subcutaneous device (Interrad Medical, Plymouth,

Minnesota, USA). In the StatLock® group, the securement device together with the catheter dressing, was changed weekly or earlier if loose, wet or soiled. In the SecurAcath® group, the securement system remained in place for the complete catheter dwell time while the catheter dressing was changed weekly or earlier if loose, wet or soiled. The allocation sequence was concealed from researchers who enrolled patients according to sequentially numbered opaque sealed envelopes which contained a card with the group assignment. The allocation concealment method was maintained, without problem. Neither patients nor assessors could be blinded because the devices were externally visible and obviously different.

Statistical analysis

A linear mixed model with a random subject effect to handle the multiple observations per subject was used to compare the time needed for the dressing change between both groups. The analysis was performed on log-transformed time values. In both groups, geometric means, their ratio and 95% confidence intervals (CI) that are obtained after backtransforming to the original scale, are reported. All patients with measurements were included in the analysis. Analysis is carried out using the SAS software, version 9.2 (SAS Institute, Inc., Cary, NC). Secondary outcomes are analysed using SPSS® version 19, (IBM® Statistics SPSS Inc, Chicago, IL). The following agreement levels on the statements about the securement device for the Likert scores are used: 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree. Results of the NRS pain scores are categorized to none (0), mild (1-2-3), moderate (4-5-6) and severe (7-8-9-10). Nominal and ordinal data were expressed in absolute numbers and percentages, and continuous data were expressed in mean and standard deviation (medians and quartiles when required). Comparisons of ordinal variables were performed by Mann-Whitney U-tests and Fisher's exact test was used to compare proportions. All tests were two-sided and P-values smaller than 0.05 were considered significant.

Results

Patient and device characteristics

We assessed 341 patients for eligibility; 105 met the inclusion criteria. After randomization, 53 patients were allocated to receive a StatLock® and 52 a SecurAcath®. PICC insertion was cancelled in three patients. No patients were lost to follow up. No reports of measurements of the dressing change procedure were available for 10 patients, 8 in the StatLock® and 2 in the SecurAcath®. group. The main reason for the missing data was the short period of time that the PICC was in place. Figure 3 shows the patients' flow.

The 2 groups were comparable in terms of patient and PICC characteristics (Table 1). The most frequent indication for PICC insertion was the administration of intravenous antibiotic therapy. The median number of catheter days was 16 days (Q1 = 10 days; Q3 = 38 days) in the StatLock® group and 21 days (Q1 = 11days; Q3 = 41 days) in the SecurAcath® group. At least one PICC had previously been inserted in 16 patients (31.4%) in the StatLock® group and in 17 patients (33.3%) in the SecurAcath® group. Of these, 1 patient in the SecurAcath® group and 3 patients in the StatLock® group confirmed that they have had the PICC secured with a SecurAcath® in the past. At insertion, most radiologists had some experience with securement device placement and used it previously ≥ 10 times in 37 (88.1%) and in 31 (73.8%) cases in the StatLock® group and in the SecurAcath® group, respectively. No procedural complications were reported. In 22 of the 31 evaluations (71.0%) in the Statlock® group and 29 of the 43 evaluations (67.3%) in the SecurAcath® group, healthcare workers who removed the PICC with securement device were experienced and removed the device already ≥ 10 times.

Table 1 Patient and PICC characteristics, and healthcare worker's level of experience with the securement device

	StatLock® (n=53)	SecurAcath® (n=52)
Sex		
Females n (%)	29 (54.7)	21 (40.4)
Median age in years (Q1 – Q3)	62 (51 – 69)	64 (50 – 71)
Reason for PICC insertion	n (%)	n (%)
Antibiotic therapy	26 (49.1)	26 (50.0)
Supportive care	18 (34.0)	13 (25.0)
Chemotherapy	9 (17.0)	11 (21.2)
Other	0 (0.0)	2 (3.8)
PICC diameter	n (%)	n (%)
4 FR (single lumen)	49 (92.5)	46 (88.5)
5 FR (double lumen)	2 (3.8)	5 (9.6)
Insertion cancelled	2 (3.8)	1 (1.9)
External length in cm at insertion	n = 51	n = 50
Mean (SD)	0.1 (0.6)	0.5 (0.9)
Min - max	-1* – 2	0 – 2
Difference in external length in cm (at dressing change compared to insertion)	n=134	n=115
Mean (SD)	0.2 (0.8)	0.1 (2.0)
Min - max	-2 – 5	- 2 – 18
Number of catheter days (catheter dwell time)	n = 51	n = 51
Total number	1541	1572
Median (Q1 – Q3)	16 (10 – 38)	21 (11 – 41)
Min - max	1 – 179	1 – 180
Radiologist's experience with securement device at insertion	n = 42 n (%)	n = 42 n (%)
First time user	1 (2.4)	4 (9.5)
< 10 times	4 (9.5)	7 (16.7)
≥ 10 times	37 (88.1)	31 (73.8)
Nurse's experience with securement device at dressing change	n = 156 n (%)	n = 159 n (%)
No experience	23 (14.7)	67 (42.2)
< 10 times	59 (37.8)	69 (43.4)
≥ 10 times	74 (47.4)	23 (14.5)
Experience with securement device at removal	n = 31 n (%)	n = 43 n (%)
First time user	2 (6.5)	7 (16.3)
< 10 times	7 (22.6)	7 (16.3)
≥ 10 times	22 (71)	29 (67.4)

*-1 cm was noted when the PICC was inserted till the thickening (of the PICC's wings) which resulted in an invisible "zero" mark sign on the PICC at the exit site

Time needed for dressing change

Time was measured during 325 dressing changes with 161 in the StatLock® group and 164 in the SecurAcath® group with a mean number of 3.74 measurements (SD 3.48) with a median of 3 measurements (Q1 = 2; Q3 = 6) and 3.35 measurements (SD 2.89) with a median of 2 measurements (Q1 = 1; Q3 = 5) measurements per patient, respectively. The maximum number of time measurements per patient was 21 in the StatLock® group and 16 in the SecurAcath® group.

In the StatLock® group, the geometric mean time needed per dressing change (Statlock® change included) was 7.3 minutes (95% CI 6.4 – 8.3) and in the SecurAcath® group 4.3 minutes (95% CI 3.8 – 4.9) (P <0.001) A boxplot shows the distribution of the time measurements in the SecurAcath® versus Statlock® group (See supplementary files). The time per procedure in the SecurAcath® group was reduced with 41% (95% CI:29% - 51%).

Migration, dislodgement, infection, pain and usability of securement device placement and removal

Table 2 summarizes the secondary outcomes. Nurses assessed catheter migration at each dressing change. They reported 2 cases of an external catheter part of ≥3 cm: 4 cm the second day after PICC placement in the StatLock® group (n=1) versus 20 cm on the day after PICC placement in the SecurAcath® group (n=1) (P= 1.00).

Dislodgement resulted in accidental PICC removal in 2 cases or 1.3/1000 catheter days (on the first and ninth day after PICC placement) in the StatLock® and 3 cases or 1.9/1000 catheter days (on the first, fourth and tenth day after PICC placement) in the SecurAcath® group (P= 1.00).

Lab-confirmed CRBSI occurred in 2 cases in the StatLock® group 34 and 84 days after PICC placement and 1 case in the SecurAcath® group 29 days after PICC placement (P=1.00).

We found statistically significant differences between pain scores in the StatLock® versus SecurAcath® group at insertion (P=0.02) and at removal (P< 0.001) but not for the total dwell time (P=0.99) nor for pain scores during dressing change (P= 0.29). In the SecurAcath® group, pain at insertion and pain during dwell time were not related (Spearman rho = - 0.064, P =0 .69), pain at

insertion and at removal were statistically significantly related (Spearman rho = 0.316, P = 0.04). Overall, the usability of of StatLock® was evaluated statistically significantly more positive than SecurAcath® at insertion and removal. At insertion, radiologists agreed to strongly agreed that the StatLock® was user-friendly (mean score 4.5) and was without difficulties to place (mean score 4.5), while the SecurAcath® was rated more neutrally regarding user-friendliness (mean score 3.4) and regarding difficulties when placing the device (mean score 3.6). Inserters agreed also that they would prefer (mean score 4.0) and would recommend (mean score 3.9) StatLock® for PICC securement. Inserters were neutral regarding the preference of SecurAcath® (mean score 3.1), and whether they would recommend (mean score 3.0) it when inserting PICCs. Nurses and physicians who removed the PICCs agreed with the statement that the StatLock® is user-friendly (mean score 4.3) and may be removed without difficulties (mean score 4.7). Healthcare workers tended to agree that SecurAcath® is user-friendly (mean score 3.6) and may be removed without difficulties (mean score 3.7). They were neutral in the preference (mean score 3.1) and the recommendation (mean score 3.3) of StatLock® and tended to agree to prefer (mean score 3.6) and recommend (mean score 3.6) SecurAcath®.

Table 2 Secondary outcomes

	StatLock®	SecurAcath®	P
Migration (≥3 cm) reported during dressing change	1/161 (0.6%)	1/164 ((0.6%)	1.00
Dislodgement resulting in PICC removal	2/47 (4.3%)	3/51 (5.9%)	1.00
Confirmed CRBSI at PICC removal	2/47 (4.3%)	1/51 (2.0%)	0.61
Pain			
At insertion	n = 47	n = 49	0.02
None (NRS = 0)	44 (93.6%)	38 (77.6%)	
Mild (NRS = 1– 2 – 3)	3 (6.4%)	8 (16.3%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.1%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.1%)	
During dressing change (highest reported score)	n = 43	n = 48	0.29
None (NRS = 0)	16 (37.2%)	20 (41.7%)	
Mild (NRS = 1– 2 – 3)	22 (51.2%)	11(22.9%)	
Moderate (NRS = 4 – 5 – 6)	5 (11.6%)	12 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	5 (10.4%)	
During dwell time	n = 31	n = 42	0.995
None (NRS = 0)	19 (61.3%)	28 (66.7%)	
Mild (NRS = 1– 2 – 3)	12 (38.7%)	11 (26.2%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.8%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.4%)	
At removal	n = 25	n = 44	<0.001
None (NRS = 0)	19 (76.0%)	20 (45.5%)	
Mild (NRS = 1– 2 – 3)	6 (24.0%)	10 (22.7%)	
Moderate (NRS = 4 – 5 – 6)	0	11 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	3 (6.8%)	
Corresponding score for evaluation of the device at insertion*	n = 47	n = 50	
I find the device user-friendly to place			
Mean (SD)	4.5 (0.6)	3.4 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	3.0 (3.0 – 4.0)	
I have no difficulties to place the device			
Mean (SD)	4.5 (0.6)	3.6 (0.9)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I prefer this device type			
Mean (SD)	4.0 (0.9)	3.1 (0.8)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
I recommend this device type to use systematically			
Mean (SD)	3.9 (0.8)	3.0 (0.6)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
Corresponding score for evaluation of the device at removal*	n = 32	n = 44	
I find the device user-friendly to remove			
Mean (SD)	4.3 (0.7)	3.6 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I have no difficulties to remove the device			
Mean (SD)	4.7 (0.7)	3.7 (1.0)	<0.001
Median (Q1-Q3)	5.0 (5.0 – 5.0)	4.0 (3.0 - 4.0)	
I prefer this device type			
Mean (SD)	3.1 (0.7)	3.6 (0.9)	0.004
Median (Q1-Q3)	3.0 (3.0 – 3.0)	3.0 (3.0 – 4.0)	
I recommend this device type to use systematically			
Mean (SD)	3.3 (0.9)	3.6 (0.9)	0.32
Median (Q1-Q3)	3.0 (3.0 – 4.0)	3.0 (3.0 – 4.0)	

* 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree; nominal variables are analysed using a Fishers Exact test, and ordinal variables using a Mann-Whitney U test.

Adverse events

Table 3 summarizes the adverse events reported during dressing change. No adverse events were reported during dressing changes in 61.5% in the StatLock® group and in 65,9% in the SecurAcath® group. Both groups were comparable regarding the number of adverse event reports (P=0.41).

Clinical signs of bleeding, oozing or a haematoma at the exit site were reported in 13% and 13.6% of dressing changes in the StatLock® group and SecurAcath® group, respectively (P=0.68). Explicitly pain reports without mentioning any other complication were similar in both groups (P=0.90). Medical Adhesive-related Skin Injury (MARSI) was reported comparable in both groups (P=0.80).

In one patient in the StatLock® group, leakage via exit site, with or without mentioning of a loose dressing, was reported during 5 dressing changes.

Table 3 Problems during dressing change

	StatLock® n = 161 n (%)	SecurAcath® n = 164 n (%)	P
None	99 (61.5)	108 (65.9)	0.42
Bleeding/oozing/haematoma	21 (13.0)	24 (14.6)	0.75
Pain at exit site	16 (9.9)	17 (10.4)	1.00
Signs of exit site infection	10 (6.2)	7 (4.3)	0.47
Medical Adhesive-related Skin Injuries	6 (3.7)	7 (4.3)	1.00
Catheter migration (≥3 cm)	1 (0.6)	1 (0.6)	1.00
Leakage and loose dressing	5 (3.1)	0	0.03
Other	3 (1.9)	0	0.12

P-values from Fishers Exact tests

Both groups were comparable regarding the number of days between reported dressing changes. The mean number of days between dressing changes was 6.8 (SD 6.0) in the StatLock® group and 7.0 (SD 7.5) in the SecurAcath® group.

End of study reasons

The reasons for the end of study were listed in table 4. PICCs were prematurely removed due to one specific complication in 21.3% of cases (n=10) in the StatLock® group and in 21.6% of cases (n=11) in the SecurAcath® group. In 4 cases in the StatLock® group the reason for removal was unknown.

	StatLock® n = 47	SecurAcath® n = 51	P
PICC REMOVED			
End of IV therapy	31 (66.0%)	35 (68.6%)	0.83
Elective exchange for tunnelled catheter	1 (2.1%)	0	0.48
Confirmed CRBSI	2 (4.3%)	1 (2.0%)	0.61
Suspected CRBSI	3 (6.4%)	6 (11.8%)	0.49
Dislodgement	2 (4.3%)	3 (5.9%)	1.00
Catheter malfunction	3 (6.4%)	1 (2.0%)	0.35
PICC IN SITU			
Patient withdraw consent*	1 (2.1%)	0	0.48
End of study time period	0	1 (2.0%)	1.00
Patient deceased	4 (8.5%)	4 (7.8%)	1.00

Table 4 Reason for end of study

* Unrelated to the securement device use; P-values from Fishers Exact test

Difficulties in removing the SecurAcath® were reported in 15 in 44 cases (34%). A local anaesthetic with lidocaine (Linisol 2%) was used 7 times for the following reasons: difficult removal (n=4), removal one day after insertion (n=1), removal after several attempts by an inexperienced nurse (n=1), and unknown (n=1). In 71.8% of cases (n=28), the SecurAcath® was cut in two just before removal.

Patients stated to choose for the same securement device in 88.5% (n=23) and 82.5% (n=33) of cases in the StatLock® and in the SecurAcath® group, respectively. The following reasons for disapproval were given in the StatLock® group: too frequent device changes (n=1) and MARSI (n=1), and in the SecurAcath® group: too painful (n=4) and causing a feeling of a burden (n=1).

Discussion

This study was based on the assertion that the change of the StatLock® device is a time-consuming and potentially risky procedure creating stress for patients and nurses. Therefore we wanted to test the hypothesis that the time for dressing change is reduced when using a securement device that does not need changing during weekly exit site care. Indeed, we found a mean reduction in time of 3 minutes per dressing change procedure in the SecurAcath® group compared to the StatLock® group ($P< 0.001$).

The ultimate goal of a securement device is: (1) to secure the catheter to prevent catheter migration and dislodgement (2) to add no CRBSI risk, (3) to be painless and (4) to be user-friendly to handle. First, catheter migration was reported at dressing change once in both groups. In the SecurAcath® group, the migration of 20 cm could be attributed to an incomplete closing of the SecurAcath® lid. Although we found 6 more migration reports, 4 patients in the SecurAcath® group (3 cm (n=3) and 13 cm (n=1) and 2 patients in the StatLock® group (once 3cm and once10 cm), we assume an incorrect measurement in all these cases. Indeed, the following external catheter length report at dressing change in the same patients didn't report any migration anymore. Moreover, in the 13 cm-migration case an chest X-Ray confirmed correct tip placement.

Second, prevention of accidental catheter dislodgement is a real clinical challenge. In our study, 3 in 5 patients with catheter dislodgement were disorientated, the fourth patient reported

that the incident occurred during the night. Finally, in the fifth patient, leakage (no blood) via the exit site loosened the catheter dressing and also the StatLock®. The 5.9% dislodgement with SecurAcath® is in line with the 7.4% of patients that removed their own catheter (n=4) or had a dislodged catheter (n=1) despite SecurAcath® securement in the study of Egan and colleagues.[6] However, the 4.6% of dislodgement we found with StatLock® is lower than the 6.1% - 12% in adults [1,7] and 30.8% in paediatrics [8] reported in other series.

Third, the incidence of confirmed CRBSI is low (0.6 per 1000 catheter days) for SecurAcath® compared to 1.5/1000 catheter days in a previous study with SecurAcath® .[6]

Fourth, we learned that pain is a concern when using SecurAcath®. We found higher pain scores with SecurAcath® than with StatLock® at insertion and removal. From our own pilot trial of 70 devices (unpublished data), we learned that at insertion, the SecurAcath® has to be placed deeply enough to avoid pain and that removal requires a certain force and dexterity. In our current RCT, none of the SecurAcath® devices required premature removal due to pain. Nonetheless, a local anaesthetic is always used at PICC insertion and could also be considered at removal of a SecurAcath®.[9] We found a mean NRS score of 1.0 ±1.8 for SecurAcath® during PICC dwell time which is comparable with the 0.7± 1.6 as previously reported.[6] The mean NRS score of 2.1 ± 2.5 at removal was slightly higher than the1.5 ± 2.5 reported in Egan's study.[6] However, patients reported the highest pain scores after dressing changes in both groups. It was clear from the free comments on the registration forms that patients, in both groups, included in their pain score the experienced pain during removal of the TSM dressing. We found no statistical significant difference between MARSI in the StatLock® (3.7%) and SecurAcath® (4.3%) group (P=0.80). Moreover it was explicitly documented in 74% of cases that the MARSI was observed along the TSM dressing surface and no indication was found to MARSI limited to neither the StatLock® nor the SecurAcath® zone. Therefore we conclude that MARSI is a minor adverse event unrelated to both types of securement device.

Finally, we found that the SecurAcath® was considered statistically significantly less user-friendly than the StatLock®. Indeed, this could be explained by the learning curve for placement and removal of SecurAcath®. However, at removal, no difference was found between the two devices regarding the recommendation to use the device systematically. An explanation could be

that nurses mostly removed the system. Potentially, they recall the drawbacks of both systems and like the weekly change for StatLock® and the more difficult removal of SecurAcath®, when scoring the recommendation to use the securement device systematically. So both systems have their advantages and disadvantages and at removal healthcare workers considered neither system ideal.

We conclude that the use of SecurAcath® is safe regarding migration, dislodgement and CRBSI, still, pain could be maximally avoided by training the users.

Our study has some methodological limitations. We included only 31% of eligible patients mainly because at the moment of PICC insertion, patients were unable to sign the ICF which might be explained by the setting of a tertiary care hospital. Though we presume no impact on our primary outcome, the needed time for dressing change, because we assume a difference in time if you need to change the securement device or not, independent of e.g. the patient's condition or the ability to speak Dutch. The analysis sample for the primary outcome contained only 92 patients despite we randomized 105 patients. However, this was compensated by patients having multiple measurements while the sample size was calculated based on a minimum of one measurement per patient. More specifically, with 3.5 as the mean number of dressing change measurements and 0.29 as the correlation between the multiple dressing change measurements from the same patient, the design effect equaled 1.725. Applying this inflation factor on the original sample size calculation at least 176 (=102*1.725) dressing change measurements in total were required to guarantee the desired power level of 80%. We also missed data at removal, especially in the StatLock® group, because these PICCs could be easily removed by staff nurses while in the SecurAcath® group, nurses of the vascular access team involved in the study removed most of the PICCs. However, we assume limited bias in the usability results because StatLock® is not associated with difficulties at removal. We observed higher pain scores at removal within the SecurAcath® group. A possible explanation could be that in this group not all devices were removed by the experienced APN from the vascular access team, as intended. However, in a post-hoc analysis we found no difference in pain scores as a function of the experience of the clinician within the SecurAcath® group.

Finally, we did not perform a full economic assessment of the use of both devices. Nevertheless, the reduced needed nursing time for dressing change with StatLock® should be taken into account in further financial evaluations. Further research should focus on strategies to reduce pain associated with SecurAcath® and also with TSM dressing's removal. Additionally, the ease of SecurAcath® removal after a long dwell time should be further investigated because in our study, the follow-up time was limited to 180 days.

SecurAcath® is a valuable and safe alternative for StatLock®. However, knowledge and training for precise placement, for smooth handling during dressing change and for a correct removal of the device, are critical.

Conclusion

We compared 2 devices for PICC securement, namely StatLock® which has to be changed weekly, and SecurAcath® which remains in place for the complete PICC dwell time. We found a statistically significant reduced time for the dressing change. In the development of new technologies, the potential of reducing nursing procedural time is an important factor given the nursing shortage.

Acknowledgement

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Legends

Figure 1 PICC secured with StatLock®

Figure 2 PICC secured with SecurAcath®

Figure 3 Patient Flow

Supplementary files
Supplementary figure: Boxplot time measurements

Contributorship statement

Hereby I confirm that all authors meet the criteria for authorship. They have approved the final article and that all those entitled to authorship are listed as authors. Please find more details for each author below.

G. A. Goossens: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

N. Grumiaux: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

C. Janssens: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

M. Jérôme : contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

S. Fieuws: contributions to conception and design, data analysis and interpretation, writing, final approval of the version to be published.

P. Moons: contributions to conception and design, data interpretation, writing, final approval of the version to be published.

M. Stas: contributions to data interpretation, writing, final approval of the version to be published.

G. Maleux: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published

Competing interests

All authors declared no conflicts of interest for this study.

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Data sharing statement

All available data can be obtained from the corresponding author.

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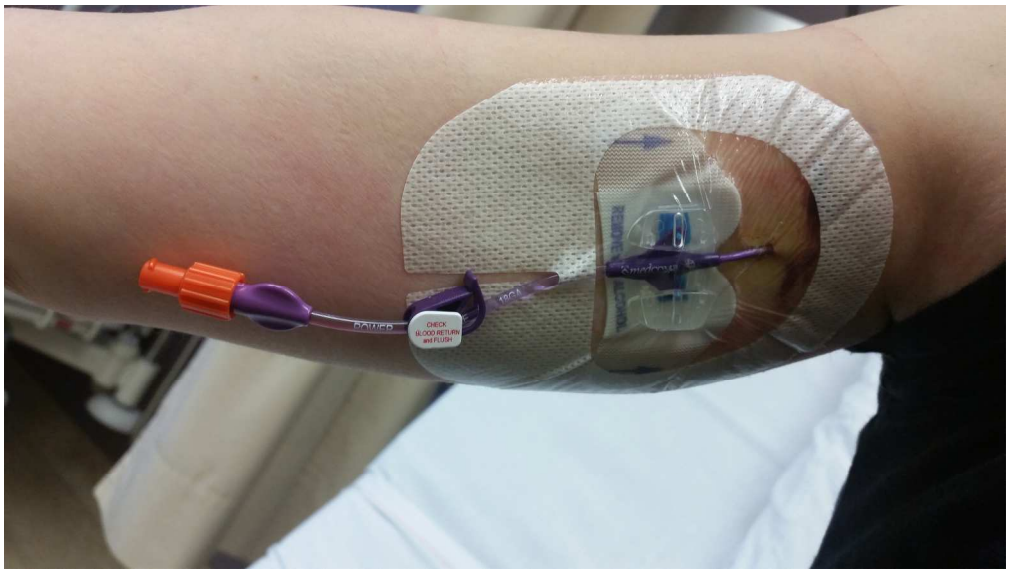

Figure 1 PICC with StatLock®

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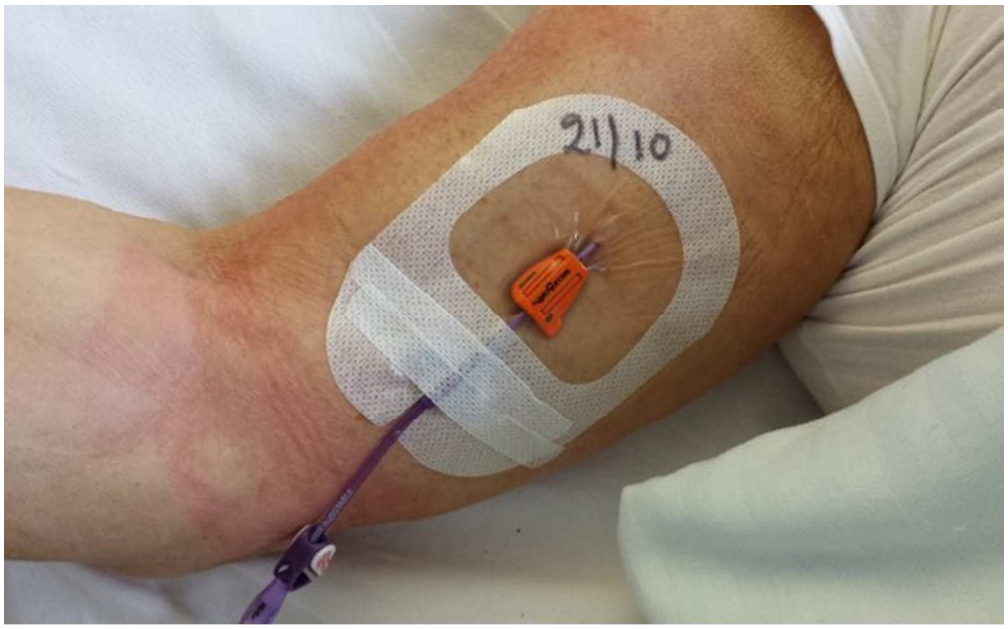


Figure 2 PICC with SecurAcath®

101x62mm (300 x 300 DPI)

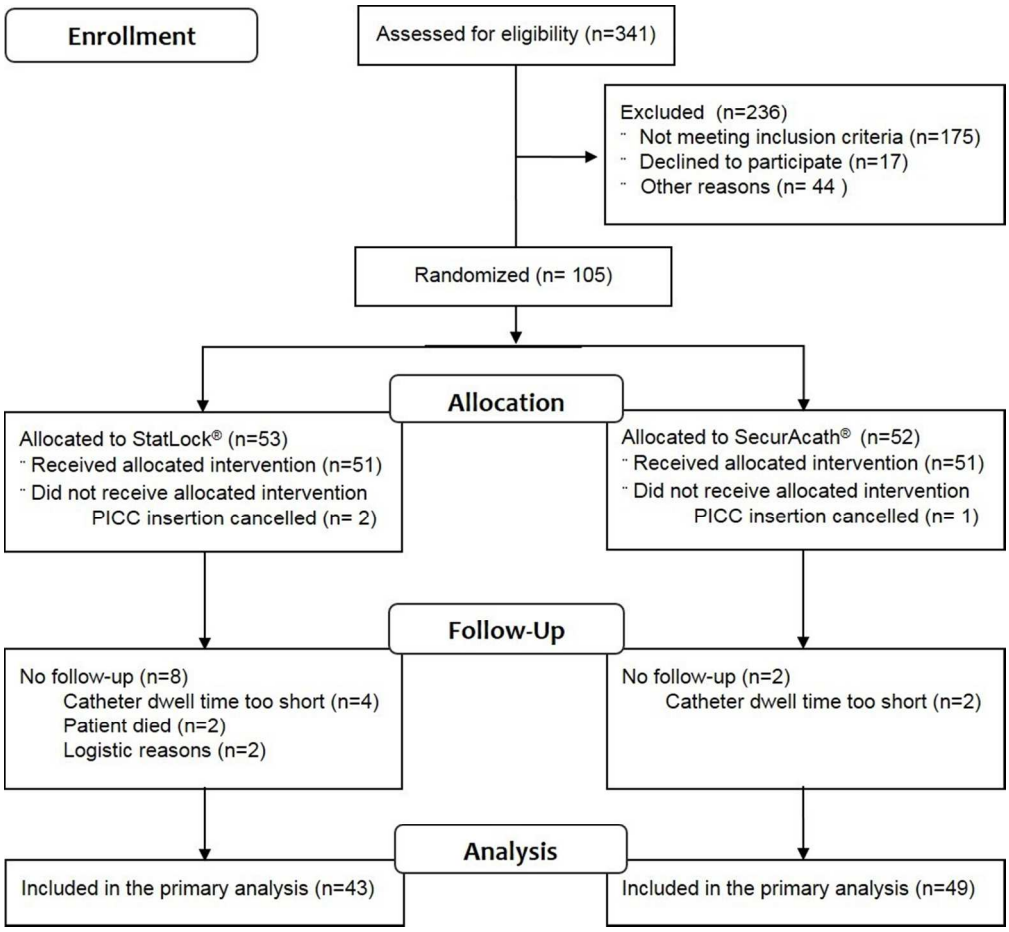
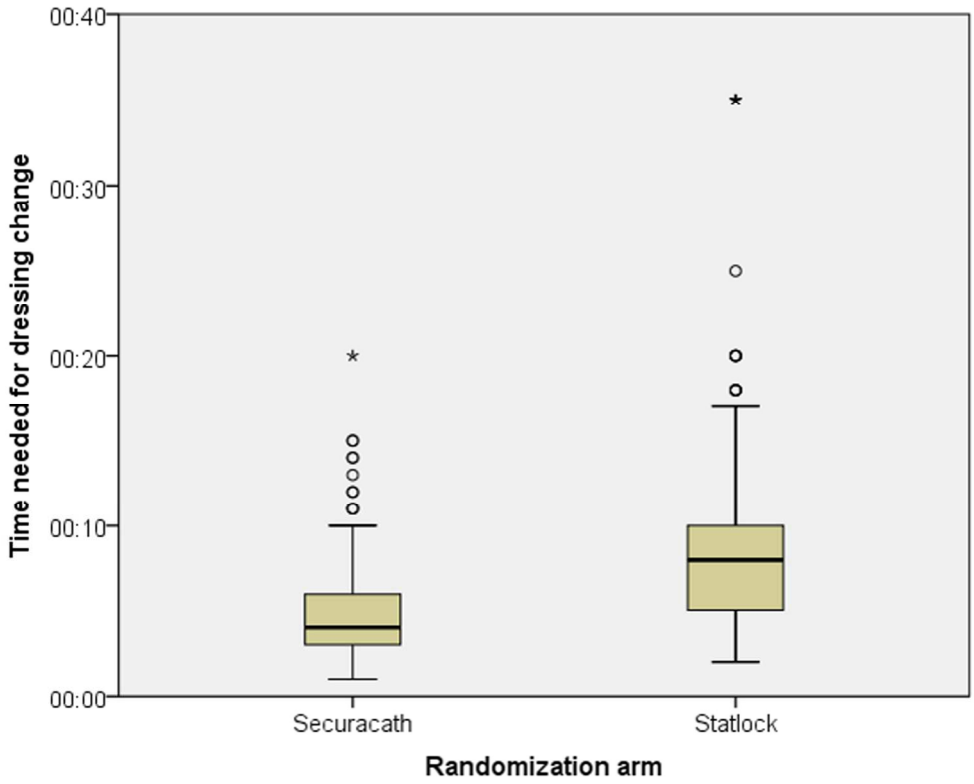


Figure 3 Patient Flow

85x78mm (300 x 300 DPI)



166x133mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NAP
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NAP
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NAP
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NAP
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NAP
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NAP
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-11 figure 1 flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	9-11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NAP
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13 Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14-21
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	14-21
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NAP
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NAP
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23-24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	23
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21-23
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	Local EC
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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Abstract

Objectives

To assess the effect on needed nursing time for dressing change.

Design, Setting, Participants

A parallel-group, open-label, randomized controlled trial in patients who are in need for a Peripherally Inserted Central Catheter insertion in one teaching hospital in Belgium. The follow-up lasted 180 days or until catheter removal, whatever came first. A computer generated table was used to allocate devices. Randomized patients were 105 adults (StatLock® n=53; SecurAcath® n=52) and primary analysis was based on all patients (n=92) with time measurements (StatLock® n=43; SecurAcath® n=49).

Interventions

StatLock® which has to be changed weekly versus SecurAcath® which could remain in place for the complete catheter dwell time.

Main outcome measure

Needed time for the dressing change at each dressing change (SecurAcath®) or at each dressing change combined with the change of the securement device (StatLock®).

Results

Median time needed for dressing change was 7.3 minutes (95% CI 6.4 minutes–8.3 minutes) in the StatLock® group and in the SecurAcath® group 4.3 minutes (95% CI 3.8 minutes-4.9 minutes) (P<0.0001). The time in the SecurAcath® group was reduced with 41% (95% CI:29%- 51%). Incidence rates of migration, dislodgement and catheter-related bloodstream infection were comparable across groups. Pain scores were higher with SecurAcath® than with StatLock® at insertion (P=0.02) and at removal (P<0.001), and comparable during dressing change (P=0.38) and during dwell time (P=0.995). User-friendliness was scored at insertion and removal. All statements regarding the user-friendliness were scored significantly higher for StatLock® than for SecurAcath® (P<0.05). Only for the statement regarding the recommending routine use of the device, which was asked at removal, no difference was found between the two devices (P=0.32).

Conclusion

Use of SecurAcath® saves time during dressing change compared to StatLock®. Training on correct placement and removal of SecurAcath® is critical to minimize pain.

Trial registration

NCT02311127

Strengths and limitations of this study

- Nursing procedural time as primary outcome measurement which is key when staff nurses are involved in device care on a regularly basis.

- Multi-professional conducted trial which evaluated needed time for care, clinical outcomes and also usability data from device inserters, device users and patients.

- First randomised controlled trial with Securacath® versus StatLock® with rigorous trial methodology to enhance reliability of results despite securement devices are not amenable to blinding.

- Full economic assessment of the use of both securement devices is lacking.

Introduction

Peripherally inserted central catheters (PICCs) are mainly used for the administration of intravenous fluids, drugs and for blood sampling. PICCs may remain in place for months and therefore may be considered mid to long-term central venous access devices. However, PICCs tend to be non-cuffed and thus at higher risk of movement, migration and total dislodgement. Consequences related to these complications include bacterial migration and catheter-related bloodstream infection, venous thrombosis, treatment delay and catheter replacement.[1] Therefore adequate securement is critical during the complete PICC dwell time. Several securement and dressing products are available.[2] However, catheters with securement systems that need to be regularly changed might be prone to dislodgement because the catheter is free-floating during securement device changes. Moreover, these adhesive-based devices may lead to medical adhesive-related skin injury (MARSI).[3] A subcutaneous catheter securement system could overcome these two disadvantages: by not requiring removal until the end of treatment and not requiring adhesive securement to skin. In addition, unlike the adhesive securement device, the subcutaneous device does not need changing, therefore the time needed for the exit site care will be shortened. Declining hospital reimbursement and nursing shortages reduces the time available for bedside nurses to complete care activities.[4] Therefore new technologies should be critically evaluated for their added value in patient care and also their impact on nursing care activities. We conducted a randomized controlled trial to compare an adhesive-backed anchor pad with a subcutaneous catheter securement system for PICCs. The objective of this study was to determine differences in nursing time for dressing change. We also investigated complications and, experiences of the healthcare worker and the patient with the securement device at PICC insertion, during dressing change and at PICC removal.

Materials and methods

Study design

This investigator-driven study is a single-centre, parallel-group, and open-label, randomized controlled trial (RCT). The study protocol was approved by hospitals local Ethics Committee (S57358), and the trial was registered at clinicaltrials.gov (NCT02311127). Patients were

recruited in the university hospitals Leuven, Belgium, where a team of interventional radiologists insert approximately 1000 PICCs per year. Advanced Practice Nurses (APN) from the vascular access team are responsible for development of procedures, staff education, research and troubleshooting in case of PICC-related problems. Patients were recruited between April 2015 and August 2015. Follow-up lasted until December 2015. Eligible patients were over 18 years old and scheduled for a PICC insertion with a polyurethane catheter, had a planned follow-up in the study centre and were able to speak and understand Dutch. Patients were excluded if they were unable to sign an informed consent form (ICF) and if they had a known allergy to nickel and/or ethylene oxide. All patients scheduled for PICC insertion in the IR suite were screened by a member of the research team for eligibility. Patients were recruited by the same team at a hospital ward or in rare occasions in the waiting room of the IR suite. Written informed consent was obtained before PICC insertion.

Outcomes and procedures

Our primary outcome measure was the time needed for the dressing change. We chose this endpoint because we hypothesized that the procedural time will be reduced if there is no need for a change of the securement device during dressing change. Moreover, we anticipated that the reduction in stress experienced by the nurse due to decreased risk of catheter dislodgement, would also contribute to decrease the time taken to change the dressing. Ward nurses measured the time taken for the dressing change at each dressing change (SecurAcath® group) or at each dressing change combined with the change of the securement device (StatLock® group). They used the clock in the patient room or a watch on a cell phone. The time was recorded in minutes starting from the moment that all material was prepared just before the removal of the catheter dressing till the end of the procedure with the application of the new catheter dressing. In both groups similar types of catheter dressing were used. At insertion, a gauze dressing, (Cosmopor® E, Hartmann) which has to be changed within 24 hours, was applied thereafter a transparent semipermeable membrane (TSM) dressing (Tegaderm™ 3M) was used. The TSM dressing was always placed over the StatLock® (Figure 1) and SecurAcath® (Figure 2).

In case of signs of exit site infection, a Biopatch® (Johnson & Johnson) was applied. Cavilon™(3M) was used in case of skin irritation.

We selected the following assessments as secondary outcomes: (1) catheter migration at dressing change, (2) catheter dislodgement resulting in premature PICC removal, (3) catheter-related bloodstream infection (CRBSI), (4) patient's pain and (5) usability of the securement devices.

At the initiation of SecurAcath® in the hospital, 6 months before study start, inserters followed a formal training on the placement of SecurAcath® and also the APN of the vascular access team were trained for device removal. The first 70 patients with a PICC secured with SecurAcath® were followed closely to monitor problems and complications with the devices, including optimising placement and removal technique. These trained interventional radiologists inserted Bard PowerPICCs (C.R. Bard Inc., Salt Lake, UT, USA) and they completed a case report form containing the indication for insertion, PICC details and perioperative problems. The experience of the radiologists who placed and, nurses and physicians who removed the securement device, was assessed on a categorical level (no experience, < 10 and ≥ 10 times). APN from the vascular access team removed the SecurAcath®. The usability of the securement device was evaluated at PICC insertion and a second time at removal by scoring 4 statements (self-developed, close-ended statements with a 5 item Likert-type scale). Patients were asked if they had previously had a PICC inserted and which securement device was used.

Patients reported pain on a Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst pain possible) at securement placement, at each dressing change, at removal for the evaluation of the removal procedure and also the complete catheter dwell time.

At dressing change, nurses described their own level of experience with the specific securement device (no experience, < 10 handlings and ≥ 10 handlings). At every dressing change, the external catheter length was measured to document eventual catheter migration. The external length was defined as zero when the zero mark sign of the first bullet marked on the PICC was at exit site for the StatLock® for the SecurAcath®, if the zero mark sign was visible just behind the SecurAcath® device, or in other words 3 cm from the exit site. Migration was defined as an accidental partial slip out of the PICC with an external catheter length of ≥ 3 cm from the

zero mark, while the PICC could be used further. We opt to define migration as a 3 cm supplementary external movement of the catheter because this is a substantial slip out of the catheter which could lead to loss of venous access.

At PICC removal, the reason for removal was recorded. Catheter dislodgement was defined as the accidental partial or total catheter slip out resulting in loss of the PICC. CRBSI was studied retrospectively by reviewing all microbial cultures available in the hospital information system. We defined laboratory-confirmed CRBSI as the presence of positive blood cultures from both the PICC and peripheral veins with the same pathogen and fever or chills in the absence of other infection sources.[5] Furthermore, specific removal data were collected: complications during removal if any, and, in the SecurAcath® group, the use of any local anaesthesia and technique of removal (cutting the device before removal or not). Patients were asked whether they would choose the same type of securement device if needed in the future (yes/no). All data were recorded on specially designed forms. Patients were followed for a maximum of 180 days or until catheter removal, whatever came first.

Calculation of the sample size

We expected less time for dressing change in the SecurAcath® group compared to the StatLock® group. We presumed, based on our observations, a time reduction of 30% for the dressing change in the SecurAcath® group due to the omission of the time spent to remove and to apply a new Statlock®. Based on a two-sided two-sample pooled t-test of a mean ratio with lognormal data, 102 subjects in total were needed to have 80% power (with α set at 5%) to detect a 30% reduction in time needed, assuming a coefficient of variation (ratio of standard deviation versus the mean) equal to 0.7. The sample size calculation was performed under the worst case scenario that only a single measurement would be available per patient.

Randomization and masking

We randomly assigned patients in a 1:1 ratio following a simple randomization procedure (computerized random numbers) to 2 groups: the StatLock® adhesive device (C.R.Bard Inc., Salt Lake, UT, USA) or the SecurAcath® subcutaneous device (Interrad Medical, Plymouth,

Minnesota, USA). In the StatLock® group, the securement device together with the catheter dressing, was changed weekly or earlier if loose, wet or soiled. In the SecurAcath® group, the securement system remained in place for the complete catheter dwell time while the catheter dressing was changed weekly or earlier if loose, wet or soiled. The allocation sequence was concealed from researchers who enrolled patients according to sequentially numbered opaque sealed envelopes which contained a card with the group assignment. The allocation concealment method was maintained, without problem. Neither patients nor assessors could be blinded because the devices were externally visible and obviously different.

Statistical analysis

A linear mixed model with a random subject effect to handle the multiple observations per subject was used to compare the time needed for the dressing change between both groups. The analysis was performed on log-transformed time values. In both groups, geometric means, their ratio and 95% confidence intervals (CI) that are obtained after backtransforming to the original scale, are reported. All patients with measurements were included in the analysis. Analysis is carried out using the SAS software, version 9.2 (SAS Institute, Inc., Cary, NC). Secondary outcomes are analysed using SPSS® version 19, (IBM® Statistics SPSS Inc, Chicago, IL). The following agreement levels on the statements about the securement device for the Likert scores are used: 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree. Results of the NRS pain scores are categorized to none (0), mild (1-2-3), moderate (4-5-6) and severe (7-8-9-10). Nominal and ordinal data were expressed in absolute numbers and percentages, and continuous data were expressed in mean and standard deviation (medians and quartiles when required). Comparisons of ordinal variables were performed by Mann-Whitney U-tests and Fisher's exact test was used to compare proportions. All tests were two-sided and P-values smaller than 0.05 were considered significant.

Results

Patient and device characteristics

We assessed 341 patients for eligibility; 105 met the inclusion criteria. After randomization, 53 patients were allocated to receive a StatLock® and 52 a SecurAcath®. PICC insertion was cancelled in three patients. No patients were lost to follow up. No reports of measurements of the dressing change procedure were available for 10 patients, 8 in the StatLock® and 2 in the SecurAcath®. group. The main reason for the missing data was that no dressing changes are done due to the short PICC dwell time. In the Figure 3 shows the patients' flow. For the primary outcome analysis we have data on 43 patients in the StatLock® group and 49 in the SecurAcath® group. For the secondary outcomes, the 51 patients per group were taken into account, however the completeness of the data is varying along the different variables. Therefore, in the tables, in the corresponding row, the total number of patients and/or measurements is shown per variable. The 2 groups were comparable in terms of patient and PICC characteristics (Table 1). The most frequent indication for PICC insertion was the administration of intravenous antibiotic therapy. The median number of catheter days was 16 days (Q1 = 10 days; Q3 = 38 days) in the StatLock® group and 21 days (Q1 = 11days; Q3 = 41 days) in the SecurAcath® group. At least one PICC had previously been inserted in 16 patients (31.4%) in the StatLock® group and in 17 patients (33.3%) in the SecurAcath® group. Of these, 1 patient in the SecurAcath® group and 3 patients in the StatLock® group confirmed that they have had the PICC secured with a SecurAcath® in the past. At insertion, most radiologists had some experience with securement device placement and used it previously ≥ 10 times in 37 (88.1%) and in 31 (73.8%) cases in the StatLock® group and in the SecurAcath® group, respectively. No procedural complications were reported. In 22 of the 31 evaluations (71.0%) in the Statlock® group and 29 of the 43 evaluations (67.3%) in the SecurAcath® group, healthcare workers who removed the PICC with securement device were experienced and removed the device already ≥ 10 times.

Table 1 Patient and PICC characteristics, and healthcare worker's level of experience with the securement device

	StatLock® (n=53)	SecurAcath® (n=52)
Sex		
Females n (%)	29 (54.7)	21 (40.4)
Median age in years (Q1 – Q3)	62 (51 – 69)	64 (50 – 71)
Reason for PICC insertion	n (%)	n (%)
Antibiotic therapy	26 (49.1)	26 (50.0)
Supportive care	18 (34.0)	13 (25.0)
Chemotherapy	9 (17.0)	11 (21.2)
Other	0 (0.0)	2 (3.8)
PICC diameter	n (%)	n (%)
4 FR (single lumen)	49 (92.5)	46 (88.5)
5 FR (double lumen)	2 (3.8)	5 (9.6)
Insertion cancelled	2 (3.8)	1 (1.9)
External length in cm at insertion	n = 51	n = 50
Mean (SD)	0.1 (0.6)	0.5 (0.9)
Min - max	-1* – 2	0 – 2
Difference in external length in cm (at dressing change compared to insertion)	n=134	n=115
Mean (SD)	0.2 (0.8)	0.1 (2.0)
Min - max	-2 – 5	- 2 – 18
Number of catheter days (catheter dwell time)	n = 51	n = 51
Total number	1541	1572
Median (Q1 – Q3)	16 (10 – 38)	21 (11 – 41)
Min - max	1 – 179	1 – 180
Radiologist's experience with securement device at insertion	n = 42 n (%)	n = 42 n (%)
First time user	1 (2.4)	4 (9.5)
< 10 times	4 (9.5)	7 (16.7)
≥ 10 times	37 (88.1)	31 (73.8)
Nurse's experience with securement device at dressing change	n = 156 n (%)	n = 159 n (%)
No experience	23 (14.7)	67 (42.2)
< 10 times	59 (37.8)	69 (43.4)
≥ 10 times	74 (47.4)	23 (14.5)
Experience with securement device at removal	n = 31 n (%)	n = 43 n (%)
First time user	2 (6.5)	7 (16.3)
< 10 times	7 (22.6)	7 (16.3)
≥ 10 times	22 (71)	29 (67.4)

*-1 cm was noted when the PICC was inserted till the thickening (of the PICC's wings) which resulted in an invisible "zero" mark sign on the PICC at the exit site

Time needed for dressing change

Time was measured during 325 dressing changes with 161 in the StatLock® group and 164 in the SecurAcath® group with a mean number of 3.74 measurements (SD 3.48) with a median of 3 measurements (Q1 = 2; Q3 = 6) and 3.35 measurements (SD 2.89) with a median of 2 measurements (Q1 = 1; Q3 = 5) measurements per patient, respectively. The maximum number of time measurements per patient was 21 in the StatLock® group and 16 in the SecurAcath® group.

In the StatLock® group, the geometric mean time needed per dressing change (Statlock® change included) was 7.3 minutes (95% CI 6.4 – 8.3) and in the SecurAcath® group 4.3 minutes (95% CI 3.8 – 4.9) (P <0.001) A boxplot shows the distribution of the time measurements in the SecurAcath® versus Statlock® group (Figure 4 Boxplot time measurements in supplementary files). The time per procedure in the SecurAcath® group was reduced with 41% (95% CI:29% - 51%).

Migration, dislodgement, infection, pain and usability of securement device placement and removal

Table 2 summarizes the secondary outcomes. Nurses assessed catheter migration at each dressing change. They reported 2 cases of an external catheter part of ≥3 cm: 4 cm the second day after PICC placement in the StatLock® group (n=1) versus 20 cm on the day after PICC placement in the SecurAcath® group (n=1) (P= 1.00).

The reason for PICC removal is unknown in 4 cases in the StatLock® group. Therefore calculations regarding PICC removal are performed on 47 instead of 51 cases in the StatLock® group. Dislodgement resulted in accidental PICC removal in 2 in 47 cases or 1.3/1000 catheter days (on the first and ninth day after PICC placement) in the StatLock® and 3 in 51 cases or 1.9/1000 catheter days (on the first, fourth and tenth day after PICC placement) in the SecurAcath® group (P= 1.00).

Lab-confirmed CRBSI occurred in 2 in 47 cases in the StatLock® group 34 and 84 days after PICC placement and in 1 in 51 cases in the SecurAcath® group 29 days after PICC placement (P=1.00).

We found statistically significant differences between pain scores in the StatLock® versus SecurAcath® group at insertion (P=0.02) and at removal (P< 0.001) but not for the total dwell time (P=0.99) nor for pain scores during dressing change (P= 0.29). In the SecurAcath® group, pain at insertion and pain during dwell time were not related (Spearman rho = - 0.064, P =0 .69), pain at insertion and at removal were statistically significantly related (Spearman rho = 0.316, P = 0.04). Overall, the usability of of StatLock® was evaluated statistically significantly more positive than SecurAcath® at insertion and removal. At insertion, radiologists agreed to strongly agreed that the StatLock® was user-friendly (mean score 4.5) and was without difficulties to place (mean score 4.5), while the SecurAcath® was rated more neutrally regarding user-friendliness (mean score 3.4) and regarding difficulties when placing the device (mean score 3.6). Inserters agreed also that they would prefer (mean score 4.0) and would recommend (mean score 3.9) StatLock® for PICC securement. Inserters were neutral regarding the preference of SecurAcath® (mean score 3.1), and whether they would recommend (mean score 3.0) it when inserting PICCs. Nurses and physicians who removed the PICCs agreed with the statement that the StatLock® is user-friendly (mean score 4.3) and may be removed without difficulties (mean score 4.7). Healthcare workers tended to agree that SecurAcath® is user-friendly (mean score 3.6) and may be removed without difficulties (mean score 3.7). They were neutral in the preference (mean score 3.1) and the recommendation (mean score 3.3) of StatLock® and tended to agree to prefer (mean score 3.6) and recommend (mean score 3.6) SecurAcath®.

Table 2 Secondary outcomes

	StatLock®	SecurAcath®	P
	n = 161	n = 164	
Migration (≥3 cm) reported during dressing change	1 (0.6%)	1 ((0.6%)	1.00
	n =47	n = 51	
Dislodgement resulting in PICC removal	2 (4.3%)	3 (5.9%)	1.00
Confirmed CRBSI at PICC removal	2 (4.3%)	1 (2.0%)	0.61
Pain			
At insertion	n = 47	n = 49	0.02
None (NRS = 0)	44 (93.6%)	38 (77.6%)	
Mild (NRS = 1– 2 – 3)	3 (6.4%)	8 (16.3%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.1%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.1%)	
During dressing change (highest reported score)	n = 43	n = 48	0.29
None (NRS = 0)	16 (37.2%)	20 (41.7%)	
Mild (NRS = 1– 2 – 3)	22 (51.2%)	11(22.9%)	
Moderate (NRS = 4 – 5 – 6)	5 (11.6%)	12 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	5 (10.4%)	
During dwell time	n = 31	n = 42	0.995
None (NRS = 0)	19 (61.3%)	28 (66.7%)	
Mild (NRS = 1– 2 – 3)	12 (38.7%)	11 (26.2%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.8%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.4%)	
At removal	n = 25	n = 44	<0.001
None (NRS = 0)	19 (76.0%)	20 (45.5%)	
Mild (NRS = 1– 2 – 3)	6 (24.0%)	10 (22.7%)	
Moderate (NRS = 4 – 5 – 6)	0	11 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	3 (6.8%)	
Corresponding score for evaluation of the device at insertion*	n = 47	n = 50	
I find the device user-friendly to place			
Mean (SD)	4.5 (0.6)	3.4 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	3.0 (3.0 – 4.0)	
I have no difficulties to place the device			
Mean (SD)	4.5 (0.6)	3.6 (0.9)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I prefer this device type			
Mean (SD)	4.0 (0.9)	3.1 (0.8)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
I recommend this device type to use systematically			
Mean (SD)	3.9 (0.8)	3.0 (0.6)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
Corresponding score for evaluation of the device at removal*	n = 32	n = 44	
I find the device user-friendly to remove			
Mean (SD)	4.3 (0.7)	3.6 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I have no difficulties to remove the device			
Mean (SD)	4.7 (0.7)	3.7 (1.0)	<0.001
Median (Q1-Q3)	5.0 (5.0 – 5.0)	4.0 (3.0 - 4.0)	
I prefer this device type			
Mean (SD)	3.1 (0.7)	3.6 (0.9)	0.004
Median (Q1-Q3)	3.0 (3.0 – 3.0)	3.0 (3.0 – 4.0)	

I recommend this device type to use systematically				
	Mean (SD)	3.3 (0.9)	3.6 (0.9)	0.32
	Median (Q1-Q3)	3.0 (3.0 – 4.0)	3.0 (3.0 – 4.0)	

* 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree; nominal variables are analysed using a Fishers Exact test, and ordinal variables using a Mann-Whitney U test.

Adverse events

Table 3 summarizes the adverse events reported during dressing change. No adverse events were reported during dressing changes in 61.5% in the StatLock® group and in 65,9% in the SecurAcath® group. Both groups were comparable regarding the number of adverse event reports (P=0.41).

Clinical signs of bleeding, oozing or a haematoma at the exit site were reported in 13% and 13.6% of dressing changes in the StatLock® group and SecurAcath® group, respectively (P=0.68). Explicitly pain reports without mentioning any other complication were similar in both groups (P=0.90). Medical Adhesive-related Skin Injury (MARSI) was reported comparable in both groups (P=0.80).

In one patient in the StatLock® group, leakage via exit site, with or without mentioning of a loose dressing, was reported during 5 dressing changes.

Table 3 Problems during dressing change

	StatLock® n = 161 n (%)	SecurAcath® n = 164 n (%)	P
None	99 (61.5)	108 (65.9)	0.42
Bleeding/oozing/haematoma	21 (13.0)	24 (14.6)	0.75
Pain at exit site	16 (9.9)	17 (10.4)	1.00
Signs of exit site infection	10 (6.2)	7 (4.3)	0.47
Medical Adhesive-related Skin Injuries	6 (3.7)	7 (4.3)	1.00
Catheter migration (≥3 cm)	1 (0.6)	1 (0.6)	1.00
Leakage and loose dressing	5 (3.1)	0	0.03
Other	3 (1.9)	0	0.12

P-values from Fishers Exact tests

Both groups were comparable regarding the number of days between reported dressing changes. The mean number of days between dressing changes was 6.8 (SD 6.0) in the StatLock® group and 7.0 (SD 7.5) in the SecurAcath® group.

End of study reasons

The reasons for the end of study were listed in table 4. In 4 cases in the StatLock® group the reason for removal was unknown. PICCs were prematurely removed due to one specific complication in 21.3% of cases (n=10) in the StatLock® group and in 21.6% of cases (n=11) in the SecurAcath® group.

	StatLock® n = 47°	SecurAcath® n = 51	P
PICC REMOVED			
End of IV therapy	31 (66.0%)	35 (68.6%)	0.83
Elective exchange for tunnelled catheter	1 (2.1%)	0	0.48
Confirmed CRBSI	2 (4.3%)	1 (2.0%)	0.61
Suspected CRBSI	3 (6.4%)	6 (11.8%)	0.49
Dislodgement	2 (4.3%)	3 (5.9%)	1.00
Catheter malfunction	3 (6.4%)	1 (2.0%)	0.35
PICC IN SITU			
Patient withdraw consent*	1 (2.1%)	0	0.48
End of study time period (>180 days)	0	1 (2.0%)	1.00
Patient deceased	4 (8.5%)	4 (7.8%)	1.00

Table 4 Reason for end of study

°in 4 cases the reason for removal was unknown; * Unrelated to the securement device use; P-values from Fishers Exact test

Difficulties in removing the SecurAcath® were reported in 15 in 44 cases (34%). A local anaesthetic with lidocaine (Linisol 2%) was used 7 times for the following reasons: difficult removal (n=4), removal one day after insertion (n=1), removal after several attempts by an inexperienced nurse (n=1), and unknown (n=1). In 71.8% of cases (n=28), the SecurAcath® was cut in two just before removal.

Patients stated to choose for the same securement device in 88.5% (n=23) and 82.5% (n=33) of cases in the StatLock® and in the SecurAcath® group, respectively. The following reasons for disapproval were given in the StatLock® group: too frequent device changes (n=1) and MARSI (n=1), and in the SecurAcath® group: too painful (n=4) and causing a feeling of a burden (n=1).

Discussion

This study was based on the assertion that the change of the StatLock® device is a time-consuming and potentially risky procedure creating stress for patients and nurses. Therefore we wanted to test the hypothesis that the time for dressing change is reduced when using a securement device that does not need changing during weekly exit site care. Indeed, we found a mean reduction in time of 3 minutes per dressing change procedure in the SecurAcath® group compared to the StatLock® group ($P< 0.001$).

The ultimate goal of a securement device is: (1) to secure the catheter to prevent catheter migration and dislodgement (2) to add no CRBSI risk, (3) to be painless and (4) to be user-friendly to handle. First, catheter migration was reported at dressing change once in both groups. In the SecurAcath® group, the migration of 20 cm could be attributed to an incomplete closing of the SecurAcath® lid. Although we found 6 more migration reports, 4 patients in the SecurAcath® group (3 cm (n=3) and 13 cm (n=1) and 2 patients in the StatLock® group (once 3cm and once10 cm), we assume an incorrect measurement in all these cases. Indeed, the following external catheter length report at dressing change in the same patients didn't report any migration anymore. Moreover, in the 13 cm-migration case an chest X-Ray confirmed correct tip placement.

Second, prevention of accidental catheter dislodgement is a real clinical challenge. In our study, 3 in 5 patients with catheter dislodgement were disorientated, the fourth patient reported

that the incident occurred during the night. Finally, in the fifth patient, leakage (no blood) via the exit site loosened the catheter dressing and also the StatLock®. The 5.9% dislodgement with SecurAcath® is in line with the 7.4% of patients that removed their own catheter (n=4) or had a dislodged catheter (n=1) despite SecurAcath® securement in the study of Egan and colleagues.[6] However, the 4.6% of dislodgement we found with StatLock® is lower than the 6.1% - 12% in adults [1,7] and 30.8% in paediatrics [8] reported in other series.

Third, the incidence of confirmed CRBSI is low (0.6 per 1000 catheter days) for SecurAcath® compared to 1.5/1000 catheter days in a previous study with SecurAcath® .[6]

Fourth, we learned that pain is a concern when using SecurAcath®. We found higher pain scores with SecurAcath® than with StatLock® at insertion and removal. From our own pilot trial of 70 devices (unpublished data), we learned that at insertion, the SecurAcath® has to be placed deeply enough to avoid pain and that removal requires a certain force and dexterity. In our current RCT, none of the SecurAcath® devices required premature removal due to pain. Nonetheless, a local anaesthetic is always used at PICC insertion and could also be considered at removal of a SecurAcath®.[9] We found a mean NRS score of 1.0 ±1.8 for SecurAcath® during PICC dwell time which is comparable with the 0.7± 1.6 as previously reported.[6] The mean NRS score of 2.1 ± 2.5 at removal was slightly higher than the1.5 ± 2.5 reported in Egan's study.[6] However, patients reported the highest pain scores after dressing changes in both groups. It was clear from the free comments on the registration forms that patients, in both groups, included in their pain score the experienced pain during removal of the TSM dressing. We found no statistical significant difference between MARSI in the StatLock® (3.7%) and SecurAcath® (4.3%) group (P=0.80). Moreover it was explicitly documented in 74% of cases that the MARSI was observed along the TSM dressing surface and no indication was found to MARSI limited to neither the StatLock® nor the SecurAcath® zone. Therefore we conclude that MARSI is a minor adverse event unrelated to both types of securement device.

Finally, we found that the SecurAcath® was considered statistically significantly less user-friendly than the StatLock®. Indeed, this could be explained by the learning curve for placement and removal of SecurAcath®. However, at removal, no difference was found between the two devices regarding the recommendation to use the device systematically. An explanation could be

that nurses mostly removed the system. Potentially, they recall the drawbacks of both systems and like the weekly change for StatLock® and the more difficult removal of SecurAcath®, when scoring the recommendation to use the securement device systematically. So both systems have their advantages and disadvantages and at removal healthcare workers considered neither system ideal.

We conclude that the use of SecurAcath® is safe regarding migration, dislodgement and CRBSI, still, pain could be maximally avoided by training the users.

Our study has some methodological limitations. We included only 31% of eligible patients mainly because at the moment of PICC insertion, patients were unable to sign the ICF which might be explained by the setting of a tertiary care hospital. Though we presume no impact on our primary outcome, the needed time for dressing change, because we assume a difference in time if you need to change the securement device or not, independent of e.g. the patient's condition or the ability to speak Dutch. The analysis sample for the primary outcome contained only 92 patients despite we randomized 105 patients. However, this was compensated by patients having multiple measurements while the sample size was calculated based on a minimum of one measurement per patient. More specifically, with 3.5 as the mean number of dressing change measurements and 0.29 as the correlation between the multiple dressing change measurements from the same patient, the design effect equalled 1.725. Applying this inflation factor on the original sample size calculation at least 176 (=102*1.725) dressing change measurements in total were required to guarantee the desired power level of 80%. We have further clarified the issue of missing data in 3/52 and 10/53 of the patients randomized to the SecurAcath® and StatLock® group, respectively. Although not being statistically significant (p=0.073) we added a sensitivity analysis to study the potential impact on the drawn conclusion for the primary outcome. To obtain a non-statistically significant difference between both groups, the time needed for dressing change for patients with missing data would have been at least 2.8 times longer for the 3 patients in the SecurAcath® group compared to the 10 patients in the StatLock® group. Since this is highly unlikely, we can safely conclude that the obtained finding on the primary outcome is robust with respect to the presence of missing data (Sensitivity analysis in supplementary files with illustration in Figure 5). We also missed data at removal, especially in

the StatLock® group, because these PICCs could be easily removed by staff nurses while in the SecurAcath® group, nurses of the vascular access team involved in the study removed most of the PICCs. However, we assume limited bias in the usability results because StatLock® is not associated with difficulties at removal. We observed higher pain scores at removal within the SecurAcath® group. A possible explanation could be that in this group not all devices were removed by the experienced APN from the vascular access team, as intended. However, in a post-hoc analysis we found no difference in pain scores as a function of the experience of the clinician within the SecurAcath® group.

Finally, we did not perform a full economic assessment of the use of both devices. Nevertheless, the reduced needed nursing time for dressing change with StatLock® should be taken into account in further financial evaluations. Further research should focus on strategies to reduce pain associated with SecurAcath® and also with TSM dressing's removal. Additionally, the ease of SecurAcath® removal after a long dwell time should be further investigated because in our study, the follow-up time was limited to 180 days.

SecurAcath® is a valuable and safe alternative for StatLock®. However, knowledge and training for precise placement, for smooth handling during dressing change and for a correct removal of the device, are critical.

Conclusion

We compared 2 devices for PICC securement, namely StatLock® which has to be changed weekly, and SecurAcath® which remains in place for the complete PICC dwell time. We found a statistically significant reduced time for the dressing change. In the development of new technologies, the potential of reducing nursing procedural time is an important factor given the nursing shortage.

Acknowledgement

We want to thank Dr. W.E. Peetermans for reviewing CRBSI in our study patients.

Legends

Figure 1 PICC secured with StatLock®

Figure 2 PICC secured with SecurAcath®

Figure 3 Patient Flow

Supplementary files

Figure 4 Boxplot time measurements

Link text: A boxplot shows the distribution of the time measurements in the SecurAcath® versus Statlock® group (Figure 4 Boxplot time measurements in supplementary files).

Supplementary information on Sensitivity analysis

Figure 5 Sensitivity analysis

Link text: Since this is highly unlikely, we can safely conclude that the obtained finding on the primary outcome is robust with respect to the presence of missing data (Sensitivity analysis in supplementary files with illustration in Figure 5).

Contributorship statement

Hereby I confirm that all authors meet the criteria for authorship. They have approved the final article and that all those entitled to authorship are listed as authors. Please find more details for each author below.

G. A. Goossens: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

N. Grumiaux: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

C. Janssens: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

M. Jérôme : contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

S. Fieuws: contributions to conception and design, data analysis and interpretation, writing, final approval of the version to be published.

P. Moons: contributions to conception and design, data interpretation, writing, final approval of the version to be published.

M. Stas: contributions to data interpretation, writing, final approval of the version to be published.

G. Maleux: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published

Competing interests

All authors declared no conflicts of interest for this study.

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Data sharing statement

All available data can be obtained from the corresponding author.

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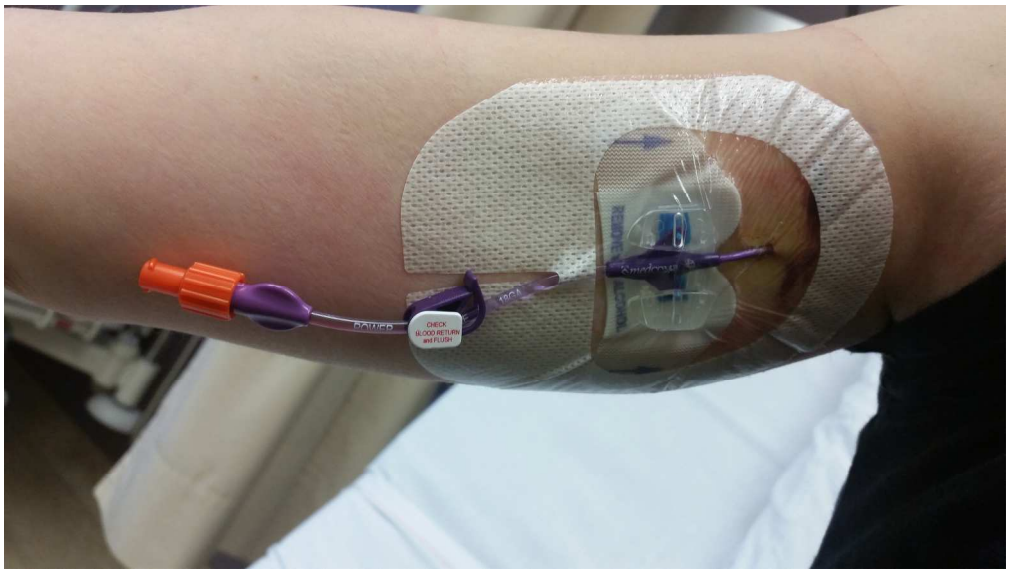

Figure 1 PICC with StatLock®

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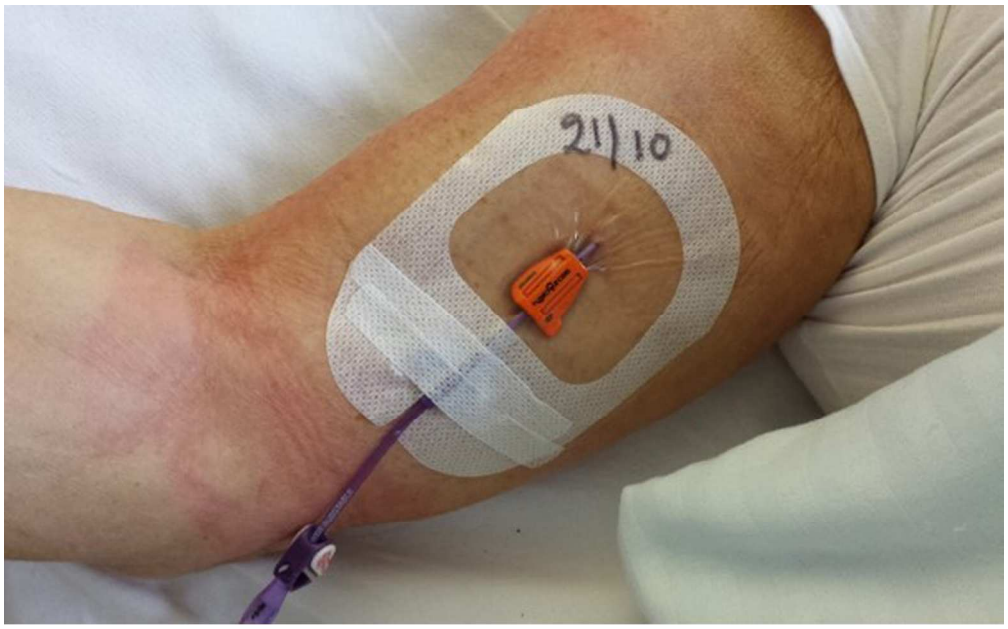

Figure 2 PICC with SecurAcath®

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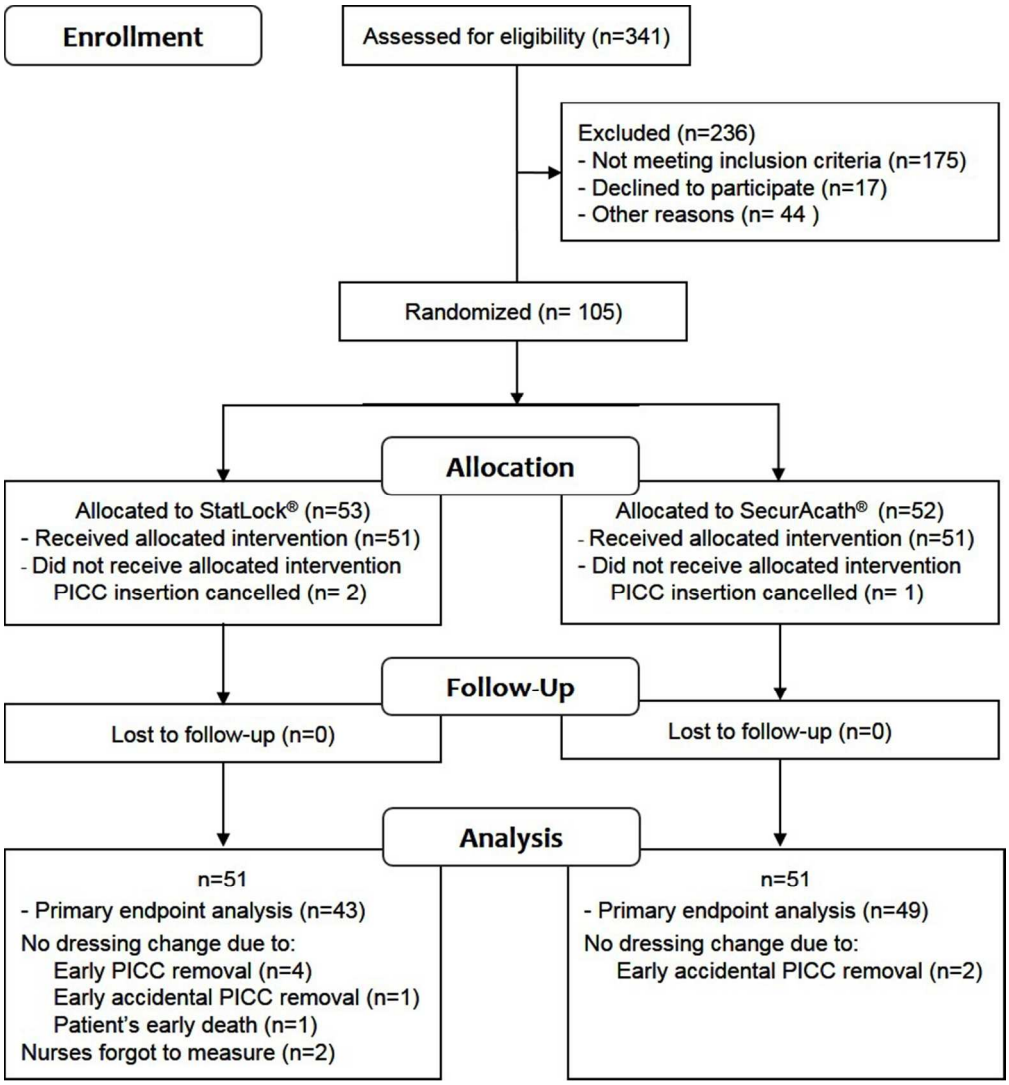
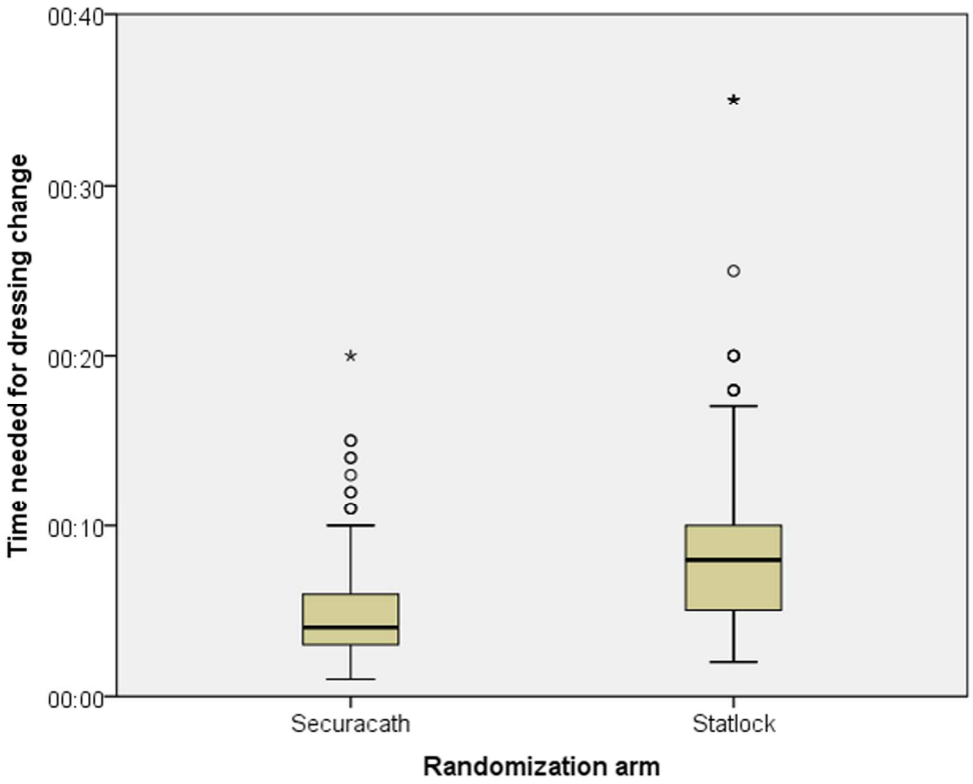


Figure 3 Patient flow

77x83mm (300 x 300 DPI)



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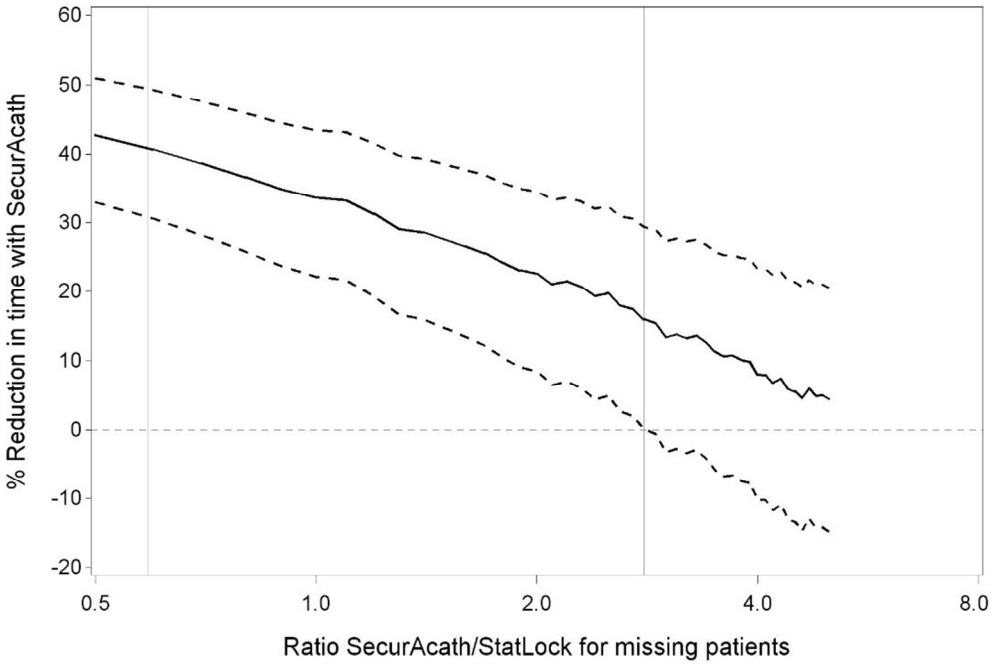

92x61mm (300 x 300 DPI)

Supplementary information on Sensitivity analysis:

Various scenarios were considered for the randomized patients without any measured time needed for dressing change (3 patients in SecurAcath® and 10 patients in Statlock® group). We repeated the analysis assuming four dressing changes per patient. Data were simulated with parameters obtained from the linear mixed model on the observed log-transformed data. For the fixed effect (i.e. the difference between both groups) various settings were explored. Specific interest was in the worst case scenarios, i.e. scenarios where the time needed for dressing change was longer in the SecurAcath® group, as opposed to the observed data. Within each considered scenario, data were simulated for the patients with missing data and the analysis was performed on the total dataset (105 patients). For each scenario, this was repeated 100 times and the mean (backtransformed from the log-scale) % reduction in time with SecurAcath® and its 95%confidence interval was calculated.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NAP
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NAP
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NAP
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NAP
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NAP
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NAP
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-11 figure 3 flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	9-11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NAP
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11 Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12-19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-19
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NAP
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NAP
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21-22
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	Local EC
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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Secondary Subject Heading:	Nursing, Health economics
Keywords:	Randomized controlled trial, Time and motion studies, MARSI, Securement device, StatLock, SecurAcath

The SecurAstaP trial: Securement with SecurAcath® versus StatLock® for Peripherally Inserted Central Catheters, a randomized open trial

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Abstract

Objectives

To assess the effect on needed nursing time for dressing change.

Design, Setting, Participants

A parallel-group, open-label, randomized controlled trial in patients who are in need for a Peripherally Inserted Central Catheter insertion in one teaching hospital in Belgium. The follow-up lasted 180 days or until catheter removal, whatever came first. A computer generated table was used to allocate devices. Randomized patients were 105 adults (StatLock® n=53; SecurAcath® n=52) and primary analysis was based on all patients (n=92) with time measurements (StatLock® n=43; SecurAcath® n=49).

Interventions

StatLock® which has to be changed weekly versus SecurAcath® which could remain in place for the complete catheter dwell time.

Main outcome measure

Needed time for the dressing change at each dressing change (SecurAcath®) or at each dressing change combined with the change of the securement device (StatLock®).

Results

Median time needed for dressing change was 7.3 minutes (95% CI 6.4 minutes–8.3 minutes) in the StatLock® group and in the SecurAcath® group 4.3 minutes (95% CI 3.8 minutes-4.9 minutes) (P<0.0001). The time in the SecurAcath® group was reduced with 41% (95% CI:29%- 51%). Incidence rates of migration, dislodgement and catheter-related bloodstream infection were comparable across groups. Pain scores were higher with SecurAcath® than with StatLock® at insertion (P=0.02) and at removal (P<0.001), and comparable during dressing change (P=0.38) and during dwell time (P=0.995). User-friendliness was scored at insertion and removal. All statements regarding the user-friendliness were scored significantly higher for StatLock® than for SecurAcath® (P<0.05). Only for the statement regarding the recommending routine use of the device, which was asked at removal, no difference was found between the two devices (P=0.32).

Conclusion

Use of SecurAcath® saves time during dressing change compared to StatLock®. Training on correct placement and removal of SecurAcath® is critical to minimize pain.

Trial registration

NCT02311127

Strengths and limitations of this study

- Nursing procedural time as primary outcome measurement which is key when staff nurses are involved in device care on a regularly basis.

- Multi-professional conducted trial which evaluated needed time for care, clinical outcomes and also usability data from device inserters, device users and patients.

- First randomised controlled trial with Securacath® versus StatLock® with rigorous trial methodology to enhance reliability of results despite securement devices are not amenable to blinding.

- Full economic assessment of the use of both securement devices is lacking.

Introduction

Peripherally inserted central catheters (PICCs) are mainly used for the administration of intravenous fluids, drugs and for blood sampling. PICCs may remain in place for months and therefore may be considered mid to long-term central venous access devices. However, PICCs tend to be non-cuffed and thus at higher risk of movement, migration and total dislodgement. Consequences related to these complications include bacterial migration and catheter-related bloodstream infection, venous thrombosis, treatment delay and catheter replacement.[1] Therefore adequate securement is critical during the complete PICC dwell time. Several securement and dressing products are available.[2] However, catheters with securement systems that need to be regularly changed might be prone to dislodgement because the catheter is free-floating during securement device changes. Moreover, these adhesive-based devices may lead to medical adhesive-related skin injury (MARSI).[3] A subcutaneous catheter securement system could overcome these two disadvantages: by not requiring removal until the end of treatment and not requiring adhesive securement to skin. In addition, unlike the adhesive securement device, the subcutaneous device does not need changing, therefore the time needed for the exit site care will be shortened. Declining hospital reimbursement and nursing shortages reduces the time available for bedside nurses to complete care activities.[4] Therefore new technologies should be critically evaluated for their added value in patient care and also their impact on nursing care activities. We conducted a randomized controlled trial to compare an adhesive-backed anchor pad with a subcutaneous catheter securement system for PICCs. The objective of this study was to determine differences in nursing time for dressing change. We also investigated complications and, experiences of the healthcare worker and the patient with the securement device at PICC insertion, during dressing change and at PICC removal.

Materials and methods

Study design

This investigator-driven study is a single-centre, parallel-group, and open-label, randomized controlled trial (RCT). The study protocol was approved by hospitals local Ethics Committee (S57358), and the trial was registered at clinicaltrials.gov (NCT02311127). Patients were

recruited in the university hospitals Leuven, Belgium, where a team of interventional radiologists insert approximately 1000 PICCs per year. Advanced Practice Nurses (APN) from the vascular access team are responsible for development of procedures, staff education, research and troubleshooting in case of PICC-related problems. Patients were recruited between April 2015 and August 2015. Follow-up lasted until December 2015. Eligible patients were over 18 years old and scheduled for a PICC insertion with a polyurethane catheter, had a planned follow-up in the study centre and were able to speak and understand Dutch. Patients were excluded if they were unable to sign an informed consent form (ICF) and if they had a known allergy to nickel and/or ethylene oxide. All patients scheduled for PICC insertion in the IR suite were screened by a member of the research team for eligibility. Patients were recruited by the same team at a hospital ward or in rare occasions in the waiting room of the IR suite. Written informed consent was obtained before PICC insertion.

Outcomes and procedures

Our primary outcome measure was the time needed for the dressing change. We chose this endpoint because we hypothesized that the procedural time will be reduced if there is no need for a change of the securement device during dressing change. Moreover, we anticipated that the reduction in stress experienced by the nurse due to decreased risk of catheter dislodgement, would also contribute to decrease the time taken to change the dressing. Ward nurses measured the time taken for the dressing change at each dressing change (SecurAcath® group) or at each dressing change combined with the change of the securement device (StatLock® group). They used the clock in the patient room or a watch on a cell phone. The time was recorded in minutes starting from the moment that all material was prepared just before the removal of the catheter dressing till the end of the procedure with the application of the new catheter dressing. In both groups similar types of catheter dressing were used. At insertion, a gauze dressing, (Cosmopor® E, Hartmann) which has to be changed within 24 hours, was applied thereafter a transparent semipermeable membrane (TSM) dressing (Tegaderm™ 3M) was used. The TSM dressing was always placed over the StatLock® (Figure 1) and SecurAcath® (Figure 2).

In case of signs of exit site infection, a Biopatch® (Johnson & Johnson) was applied. Cavilon™(3M) was used in case of skin irritation.

We selected the following assessments as secondary outcomes: (1) catheter migration at dressing change, (2) catheter dislodgement resulting in premature PICC removal, (3) catheter-related bloodstream infection (CRBSI), (4) patient's pain and (5) usability of the securement devices.

At the initiation of SecurAcath® in the hospital, 6 months before study start, inserters followed a formal training on the placement of SecurAcath® and also the APN of the vascular access team were trained for device removal. The first 70 patients with a PICC secured with SecurAcath® were followed closely to monitor problems and complications with the devices, including optimising placement and removal technique. These trained interventional radiologists inserted Bard PowerPICCs (C.R. Bard Inc., Salt Lake, UT, USA) and they completed a case report form containing the indication for insertion, PICC details and perioperative problems. The experience of the radiologists who placed and, nurses and physicians who removed the securement device, was assessed on a categorical level (no experience, < 10 and ≥ 10 times). APN from the vascular access team removed the SecurAcath®. The usability of the securement device was evaluated at PICC insertion and a second time at removal by scoring 4 statements (self-developed, close-ended statements with a 5 item Likert-type scale). Patients were asked if they had previously had a PICC inserted and which securement device was used.

Patients reported pain on a Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst pain possible) at securement placement, at each dressing change, at removal for the evaluation of the removal procedure and also the complete catheter dwell time.

At dressing change, nurses described their own level of experience with the specific securement device (no experience, < 10 handlings and ≥ 10 handlings). At every dressing change, the external catheter length was measured to document eventual catheter migration. The external length was defined as zero when the zero mark sign of the first bullet marked on the PICC was at exit site for the StatLock® for the SecurAcath®, if the zero mark sign was visible just behind the SecurAcath® device, or in other words 3 cm from the exit site. Migration was defined as an accidental partial slip out of the PICC with an external catheter length of ≥ 3 cm from the

zero mark, while the PICC could be used further. We opt to define migration as a 3 cm supplementary external movement of the catheter because this is a substantial slip out of the catheter which could lead to loss of venous access.

At PICC removal, the reason for removal was recorded. Catheter dislodgement was defined as the accidental partial or total catheter slip out resulting in loss of the PICC. CRBSI was studied retrospectively by reviewing all microbial cultures available in the hospital information system. We defined laboratory-confirmed CRBSI as the presence of positive blood cultures from both the PICC and peripheral veins with the same pathogen and fever or chills in the absence of other infection sources.[5] Furthermore, specific removal data were collected: complications during removal if any, and, in the SecurAcath® group, the use of any local anaesthesia and technique of removal (cutting the device before removal or not). Patients were asked whether they would choose the same type of securement device if needed in the future (yes/no). All data were recorded on specially designed forms. Patients were followed for a maximum of 180 days or until catheter removal, whatever came first.

Calculation of the sample size

We expected less time for dressing change in the SecurAcath® group compared to the StatLock® group. We presumed, based on our observations, a time reduction of 30% for the dressing change in the SecurAcath® group due to the omission of the time spent to remove and to apply a new Statlock®. Based on a two-sided two-sample pooled t-test of a mean ratio with lognormal data, 102 subjects in total were needed to have 80% power (with α set at 5%) to detect a 30% reduction in time needed, assuming a coefficient of variation (ratio of standard deviation versus the mean) equal to 0.7. The sample size calculation was performed under the worst case scenario that only a single measurement would be available per patient.

Randomization and masking

We randomly assigned patients in a 1:1 ratio following a simple randomization procedure (computerized random numbers) to 2 groups: the StatLock® adhesive device (C.R.Bard Inc., Salt Lake, UT, USA) or the SecurAcath® subcutaneous device (Interrad Medical, Plymouth,

Minnesota, USA). In the StatLock® group, the securement device together with the catheter dressing, was changed weekly or earlier if loose, wet or soiled. In the SecurAcath® group, the securement system remained in place for the complete catheter dwell time while the catheter dressing was changed weekly or earlier if loose, wet or soiled. The allocation sequence was concealed from researchers who enrolled patients according to sequentially numbered opaque sealed envelopes which contained a card with the group assignment. The allocation concealment method was maintained, without problem. Neither patients nor assessors could be blinded because the devices were externally visible and obviously different.

Statistical analysis

A linear mixed model with a random subject effect to handle the multiple observations per subject was used to compare the time needed for the dressing change between both groups. The analysis was performed on log-transformed time values. In both groups, geometric means, their ratio and 95% confidence intervals (CI) that are obtained after backtransforming to the original scale, are reported. All patients with measurements were included in the analysis. Analysis is carried out using the SAS software, version 9.2 (SAS Institute, Inc., Cary, NC). Secondary outcomes are analysed using SPSS® version 19, (IBM® Statistics SPSS Inc, Chicago, IL). The following agreement levels on the statements about the securement device for the Likert scores are used: 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree. Results of the NRS pain scores are categorized to none (0), mild (1-2-3), moderate (4-5-6) and severe (7-8-9-10). Nominal and ordinal data were expressed in absolute numbers and percentages, and continuous data were expressed in mean and standard deviation (medians and quartiles when required). The proportion of dressing changes with a reported clinical problem, was compared between both groups using a logistic regression model with generalised estimating equations (GEE) based on an independent working correlation matrix to handle the correlation between the multiple dressing changes within the same patient. Given the low number of events for most specific problems no statistical tests correcting for the within-patient correlation were reported for these. Comparisons of ordinal variables were performed by Mann-Whitney U-tests and Fisher's

exact test was used to compare proportions. All tests were two-sided and P-values smaller than 0.05 were considered significant.

Results

Patient and device characteristics

We assessed 341 patients for eligibility; 105 met the inclusion criteria. After randomization, 53 patients were allocated to receive a StatLock® and 52 a SecurAcath®. PICC insertion was cancelled in three patients. No patients were lost to follow up. No reports of measurements of the dressing change procedure were available for 10 patients, 8 in the StatLock® and 2 in the SecurAcath®. group. The main reason for the missing data was that no dressing changes are done due to the short PICC dwell time. In the Figure 3 shows the patients' flow. For the primary outcome analysis we have data on 43 patients in the StatLock® group and 49 in the SecurAcath® group. For the secondary outcomes, the 51 patients per group were taken into account, however the completeness of the data is varying along the different variables. Therefore, in the tables, in the corresponding row, the total number of patients and/or measurements is shown per variable. The 2 groups were comparable in terms of patient and PICC characteristics (Table 1). The most frequent indication for PICC insertion was the administration of intravenous antibiotic therapy. The median number of catheter days was 16 days (Q1 = 10 days; Q3 = 38 days) in the StatLock® group and 21 days (Q1 = 11days; Q3 = 41 days) in the SecurAcath® group. At least one PICC had previously been inserted in 16 patients (31.4%) in the StatLock® group and in 17 patients (33.3%) in the SecurAcath® group. Of these, 1 patient in the SecurAcath® group and 3 patients in the StatLock® group confirmed that they have had the PICC secured with a SecurAcath® in the past. At insertion, most radiologists had some experience with securement device placement and used it previously ≥ 10 times in 37 (88.1%) and in 31 (73.8%) cases in the StatLock® group and in the SecurAcath® group, respectively. No procedural complications were reported. In 22 of the 31 evaluations (71.0%) in the Statlock® group and 29 of the 43 evaluations (67.3%) in the SecurAcath® group, healthcare workers who removed the PICC with securement device were experienced and removed the device already ≥ 10 times.

Table 1 Patient and PICC characteristics, and healthcare worker's level of experience with the securement device

	StatLock® (n=53)	SecurAcath® (n=52)
Sex		
Females n (%)	29 (54.7)	21 (40.4)
Median age in years (Q1 – Q3)	62 (51 – 69)	64 (50 – 71)
Reason for PICC insertion	n (%)	n (%)
Antibiotic therapy	26 (49.1)	26 (50.0)
Supportive care	18 (34.0)	13 (25.0)
Chemotherapy	9 (17.0)	11 (21.2)
Other	0 (0.0)	2 (3.8)
PICC diameter	n (%)	n (%)
4 FR (single lumen)	49 (92.5)	46 (88.5)
5 FR (double lumen)	2 (3.8)	5 (9.6)
Insertion cancelled	2 (3.8)	1 (1.9)
External length in cm at insertion	n = 51	n = 50
Mean (SD)	0.1 (0.6)	0.5 (0.9)
Min - max	-1* – 2	0 – 2
Difference in external length in cm (at dressing change compared to insertion)	n=134	n=115
Mean (SD)	0.2 (0.8)	0.1 (2.0)
Min - max	-2 – 5	- 2 – 18
Number of catheter days (catheter dwell time)	n = 51	n = 51
Total number	1541	1572
Median (Q1 – Q3)	16 (10 – 38)	21 (11 – 41)
Min - max	1 – 179	1 – 180
Radiologist's experience with securement device at insertion	n = 42 n (%)	n = 42 n (%)
First time user	1 (2.4)	4 (9.5)
< 10 times	4 (9.5)	7 (16.7)
≥ 10 times	37 (88.1)	31 (73.8)
Nurse's experience with securement device at dressing change	n = 156 n (%)	n = 159 n (%)
No experience	23 (14.7)	67 (42.2)
< 10 times	59 (37.8)	69 (43.4)
≥ 10 times	74 (47.4)	23 (14.5)
Experience with securement device at removal	n = 31 n (%)	n = 43 n (%)
First time user	2 (6.5)	7 (16.3)
< 10 times	7 (22.6)	7 (16.3)
≥ 10 times	22 (71)	29 (67.4)

*-1 cm was noted when the PICC was inserted till the thickening (of the PICC's wings) which resulted in an invisible "zero" mark sign on the PICC at the exit site

Time needed for dressing change

Time was measured during 325 dressing changes with 161 in the StatLock® group and 164 in the SecurAcath® group with a mean number of 3.74 measurements (SD 3.48) with a median of 3 measurements (Q1 = 2; Q3 = 6) and 3.35 measurements (SD 2.89) with a median of 2 measurements (Q1 = 1; Q3 = 5) measurements per patient, respectively. The maximum number of time measurements per patient was 21 in the StatLock® group and 16 in the SecurAcath® group.

In the StatLock® group, the geometric mean time needed per dressing change (Statlock® change included) was 7.3 minutes (95% CI 6.4 – 8.3) and in the SecurAcath® group 4.3 minutes (95% CI 3.8 – 4.9) (P <0.001) A boxplot shows the distribution of the time measurements in the SecurAcath® versus Statlock® group (Supplementary Figure 1 Boxplot time measurements). The time per procedure in the SecurAcath® group was reduced with 41% (95% CI:29% - 51%).

Migration, dislodgement, infection, pain and usability of securement device placement and removal

Table 2 summarizes the secondary outcomes. Nurses assessed catheter migration at each dressing change. They reported 2 cases of an external catheter part of ≥3 cm: 4 cm the second day after PICC placement in the StatLock® group (n=1) versus 20 cm on the day after PICC placement in the SecurAcath® group (n=1) (P= 1.00).

The reason for PICC removal is unknown in 4 cases in the StatLock® group. Therefore calculations regarding PICC removal are performed on 47 instead of 51 cases in the StatLock® group. Dislodgement resulted in accidental PICC removal in 2 in 47 cases or 1.3/1000 catheter days (on the first and ninth day after PICC placement) in the StatLock® and 3 in 51 cases or 1.9/1000 catheter days (on the first, fourth and tenth day after PICC placement) in the SecurAcath® group (P= 1.00).

Lab-confirmed CRBSI occurred in 2 in 47 cases in the StatLock® group 34 and 84 days after PICC placement and in 1 in 51 cases in the SecurAcath® group 29 days after PICC placement (P=1.00).

We found statistically significant differences between pain scores in the StatLock® versus SecurAcath® group at insertion (P=0.02) and at removal (P< 0.001) but not for the total dwell time (P=0.99) nor for pain scores during dressing change (P= 0.29). In the SecurAcath® group, pain at insertion and pain during dwell time were not related (Spearman rho = - 0.064, P =0 .69), pain at insertion and at removal were statistically significantly related (Spearman rho = 0.316, P = 0.04). Overall, the usability of of StatLock® was evaluated statistically significantly more positive than SecurAcath® at insertion and removal. At insertion, radiologists agreed to strongly agreed that the StatLock® was user-friendly (mean score 4.5) and was without difficulties to place (mean score 4.5), while the SecurAcath® was rated more neutrally regarding user-friendliness (mean score 3.4) and regarding difficulties when placing the device (mean score 3.6). Inserters agreed also that they would prefer (mean score 4.0) and would recommend (mean score 3.9) StatLock® for PICC securement. Inserters were neutral regarding the preference of SecurAcath® (mean score 3.1), and whether they would recommend (mean score 3.0) it when inserting PICCs. Nurses and physicians who removed the PICCs agreed with the statement that the StatLock® is user-friendly (mean score 4.3) and may be removed without difficulties (mean score 4.7). Healthcare workers tended to agree that SecurAcath® is user-friendly (mean score 3.6) and may be removed without difficulties (mean score 3.7). They were neutral in the preference (mean score 3.1) and the recommendation (mean score 3.3) of StatLock® and tended to agree to prefer (mean score 3.6) and recommend (mean score 3.6) SecurAcath®.

Table 2 Secondary outcomes

	StatLock®	SecurAcath®	P
	n = 161	n = 164	
Migration (≥3 cm) reported during dressing change	1 (0.6%)	1 ((0.6%)	1.00
	n =47	n = 51	
Dislodgement resulting in PICC removal	2 (4.3%)	3 (5.9%)	1.00
Confirmed CRBSI at PICC removal	2 (4.3%)	1 (2.0%)	0.61
Pain			
At insertion	n = 47	n = 49	0.02
None (NRS = 0)	44 (93.6%)	38 (77.6%)	
Mild (NRS = 1– 2 – 3)	3 (6.4%)	8 (16.3%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.1%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.1%)	
During dressing change (highest reported score)	n = 43	n = 48	0.29
None (NRS = 0)	16 (37.2%)	20 (41.7%)	
Mild (NRS = 1– 2 – 3)	22 (51.2%)	11(22.9%)	
Moderate (NRS = 4 – 5 – 6)	5 (11.6%)	12 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	5 (10.4%)	
During dwell time	n = 31	n = 42	0.995
None (NRS = 0)	19 (61.3%)	28 (66.7%)	
Mild (NRS = 1– 2 – 3)	12 (38.7%)	11 (26.2%)	
Moderate (NRS = 4 – 5 – 6)	0	2 (4.8%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	1 (2.4%)	
At removal	n = 25	n = 44	<0.001
None (NRS = 0)	19 (76.0%)	20 (45.5%)	
Mild (NRS = 1– 2 – 3)	6 (24.0%)	10 (22.7%)	
Moderate (NRS = 4 – 5 – 6)	0	11 (25.0%)	
Severe (NRS = 7 – 8 – 9 – 10)	0	3 (6.8%)	
Corresponding score for evaluation of the device at insertion*	n = 47	n = 50	
I find the device user-friendly to place			
Mean (SD)	4.5 (0.6)	3.4 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	3.0 (3.0 – 4.0)	
I have no difficulties to place the device			
Mean (SD)	4.5 (0.6)	3.6 (0.9)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I prefer this device type			
Mean (SD)	4.0 (0.9)	3.1 (0.8)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
I recommend this device type to use systematically			
Mean (SD)	3.9 (0.8)	3.0 (0.6)	<0.001
Median (Q1-Q3)	4.0 (3.0 – 5.0)	3.0 (3.0 – 3.0)	
Corresponding score for evaluation of the device at removal*	n = 32	n = 44	
I find the device user-friendly to remove			
Mean (SD)	4.3 (0.7)	3.6 (1.0)	<0.001
Median (Q1-Q3)	5.0 (4.0 – 5.0)	4.0 (3.0 – 4.0)	
I have no difficulties to remove the device			
Mean (SD)	4.7 (0.7)	3.7 (1.0)	<0.001
Median (Q1-Q3)	5.0 (5.0 – 5.0)	4.0 (3.0 - 4.0)	
I prefer this device type			
Mean (SD)	3.1 (0.7)	3.6 (0.9)	0.004
Median (Q1-Q3)	3.0 (3.0 – 3.0)	3.0 (3.0 – 4.0)	

I recommend this device type to use systematically			
Mean (SD)	3.3 (0.9)	3.6 (0.9)	0.32
Median (Q1-Q3)	3.0 (3.0 – 4.0)	3.0 (3.0 – 4.0)	

* 1:strongly disagree; 2: disagree; 3: neutral; 4: agree; 5: strongly agree; nominal variables are analysed using a Fishers Exact test, and ordinal variables using a Mann-Whitney U test.

Adverse events

Table 3 summarizes the adverse events reported during dressing change. No adverse events were reported during dressing changes in 61.5% in the StatLock® group and in 65.9% in the SecurAcath® group. Both groups were comparable regarding the number of adverse event reports (P=0.53).

Clinical signs of bleeding, oozing or a haematoma at the exit site were reported in 13% and 14.6% of dressing changes in the StatLock® group and SecurAcath® group, respectively. Explicitly pain reports without mentioning any other complication were similar in both groups. Medical Adhesive-related Skin Injury (MARSI) was reported comparable in both groups.

In one patient in the StatLock® group, leakage via exit site, with or without mentioning of a loose dressing, was reported during 5 dressing changes.

Table 3 Problems during dressing change

	StatLock® n = 161 n (%)	SecurAcath® n = 164 n (%)	P
None	99 (61.5)	108 (65.9)	0.53
Bleeding/oozing/haematoma	21 (13.0)	24 (14.6)	
Pain at exit site	16 (9.9)	17 (10.4)	
Signs of exit site infection	10 (6.2)	7 (4.3)	
Medical Adhesive-related Skin Injuries	6 (3.7)	7 (4.3)	
Catheter migration (≥3 cm)	1 (0.6)	1 (0.6)	
Leakage and loose dressing	5 (3.1)	0	
Other	3 (1.9)	0	

P-values from logistic regression with GEE

Both groups were comparable regarding the number of days between reported dressing changes. The mean number of days between dressing changes was 6.8 (SD 6.0) in the StatLock® group and 7.0 (SD 7.5) in the SecurAcath® group.

End of study reasons

The reasons for the end of study were listed in table 4. In 4 cases in the StatLock® group the reason for removal was unknown. PICCs were prematurely removed due to one specific complication in 21.3% of cases (n=10) in the StatLock® group and in 21.6% of cases (n=11) in the SecurAcath® group.

	StatLock® n = 47°	SecurAcath® n = 51	P
PICC REMOVED			
End of IV therapy	31 (66.0%)	35 (68.6%)	0.83
Elective exchange for tunnelled catheter	1 (2.1%)	0	0.48
Confirmed CRBSI	2 (4.3%)	1 (2.0%)	0.61
Suspected CRBSI	3 (6.4%)	6 (11.8%)	0.49
Dislodgement	2 (4.3%)	3 (5.9%)	1.00
Catheter malfunction	3 (6.4%)	1 (2.0%)	0.35
PICC IN SITU			
Patient withdraw consent*	1 (2.1%)	0	0.48
End of study time period (>180 days)	0	1 (2.0%)	1.00
Patient deceased	4 (8.5%)	4 (7.8%)	1.00

Table 4 Reason for end of study

°In 4 cases the reason for removal was unknown; * Unrelated to the securement device use; P-values from Fishers Exact test

Difficulties in removing the SecurAcath® were reported in 15 in 44 cases (34%). A local anaesthetic with lidocaine (Linisol 2%) was used 7 times for the following reasons: difficult removal (n=4), removal one day after insertion (n=1), removal after several attempts by an inexperienced nurse (n=1), and unknown (n=1). In 71.8% of cases (n=28), the SecurAcath® was cut in two just before removal.

Patients stated to choose for the same securement device in 88.5% (n=23) and 82.5% (n=33) of cases in the StatLock® and in the SecurAcath® group, respectively. The following reasons for disapproval were given in the StatLock® group: too frequent device changes (n=1) and MARSI (n=1), and in the SecurAcath® group: too painful (n=4) and causing a feeling of a burden (n=1).

Discussion

This study was based on the assertion that the change of the StatLock® device is a time-consuming and potentially risky procedure creating stress for patients and nurses. Therefore we wanted to test the hypothesis that the time for dressing change is reduced when using a securement device that does not need changing during weekly exit site care. Indeed, we found a mean reduction in time of 3 minutes per dressing change procedure in the SecurAcath® group compared to the StatLock® group ($P< 0.001$).

The ultimate goal of a securement device is: (1) to secure the catheter to prevent catheter migration and dislodgement (2) to add no CRBSI risk, (3) to be painless and (4) to be user-friendly to handle. First, catheter migration was reported at dressing change once in both groups. In the SecurAcath® group, the migration of 20 cm could be attributed to an incomplete closing of the SecurAcath® lid. Although we found 6 more migration reports, 4 patients in the SecurAcath® group (3 cm (n=3) and 13 cm (n=1) and 2 patients in the StatLock® group (once 3cm and once10 cm), we assume an incorrect measurement in all these cases. Indeed, the following external catheter length report at dressing change in the same patients didn't report any migration anymore. Moreover, in the 13 cm-migration case an chest X-Ray confirmed correct tip placement. Prevention of accidental catheter dislodgement is a real clinical challenge. In our study, 3 in 5 patients with catheter dislodgement were disorientated, the fourth patient reported that the

incident occurred during the night. Finally, in the fifth patient, leakage (no blood) via the exit site loosened the catheter dressing and also the StatLock®. The 5.9% dislodgement with SecurAcath® is in line with the 7.4% of patients that removed their own catheter (n=4) or had a dislodged catheter (n=1) despite SecurAcath® securement in the study of Egan and colleagues.[6] However, the 4.6% of dislodgement we found with StatLock® is lower than the 6.1% - 12% in adults [1,7] and 30.8% in paediatrics [8] reported in other series.

Second, the incidence of confirmed CRBSI is low (0.6 per 1000 catheter days) for SecurAcath® compared to 1.5/1000 catheter days in a previous study with SecurAcath® .[6]

Third, we learned that pain is a concern when using SecurAcath®. We found higher pain scores with SecurAcath® than with StatLock® at insertion and removal. From our own pilot trial of 70 devices (unpublished data), we learned that at insertion, the SecurAcath® has to be placed deeply enough to avoid pain and that removal requires a certain force and dexterity. In our current RCT, none of the SecurAcath® devices required premature removal due to pain. Nonetheless, a local anaesthetic is always used at PICC insertion and could also be considered at removal of a SecurAcath®.[9] We found a mean NRS score of 1.0 ±1.8 for SecurAcath® during PICC dwell time which is comparable with the 0.7± 1.6 as previously reported.[6] The mean NRS score of 2.1 ± 2.5 at removal was slightly higher than the1.5 ± 2.5 reported in Egan's study.[6] However, patients reported the highest pain scores after dressing changes in both groups. It was clear from the free comments on the registration forms that patients, in both groups, included in their pain score the experienced pain during removal of the TSM dressing. MARSI reports were similar in the two groups: 3.7% in the StatLock® and 4.3% SecurAcath® group. Moreover MARSI observation along the TSM dressing surface was explicitly documented in 74% of MARSI reports and no indication was found to MARSI limited to neither the StatLock® nor the SecurAcath® zone. Therefore we conclude that MARSI is a minor adverse event unrelated to both types of securement device.

Fourth, we found that the SecurAcath® was considered statistically significantly less user-friendly than the StatLock®. Indeed, this could be explained by the learning curve for placement and removal of SecurAcath®. However, at removal, no difference was found between the two devices regarding the recommendation to use the device systematically. An explanation could be

that nurses mostly removed the system. Potentially, they recall the drawbacks of both systems and like the weekly change for StatLock® and the more difficult removal of SecurAcath®, when scoring the recommendation to use the securement device systematically. So both systems have their advantages and disadvantages and at removal healthcare workers considered neither system ideal.

We conclude that the use of SecurAcath® is safe regarding migration, dislodgement and CRBSI, still, pain could be maximally avoided by training the users.

Our study has some methodological limitations which might affect the generalisability of the trial findings. First, we included only 31% of eligible patients mainly because at the moment of PICC insertion, patients were unable to sign the ICF which might be explained by the setting of a tertiary care hospital. Though we presume no impact on our primary outcome, the needed time for dressing change, because we assume a difference in time if you need to change the securement device or not, independent of e.g. the patient's condition or the ability to speak Dutch. We expect that nurses working in a teaching hospital are more experienced in the use of both securement devices. If so, the dressing change time will be, especially in the StaLock® group due to the difficult manipulation, lower than expected in the general population. So, potentially, the effect size might be larger in the general population. Second, the analysis sample for the primary outcome contained only 92 patients despite we randomized 105 patients. However, this was compensated by patients having multiple measurements while the sample size was calculated based on a minimum of one measurement per patient. More specifically, with 3.5 as the mean number of dressing change measurements and 0.29 as the correlation between the multiple dressing change measurements from the same patient, the design effect equalled 1.725. Applying this inflation factor on the original sample size calculation at least 176 (=102*1.725) dressing change measurements in total were required to guarantee the desired power level of 80%. We have further clarified the issue of missing data in 3/52 and 10/53 of the patients randomized to the SecurAcath® and StatLock® group, respectively. Although not being statistically significant (p=0.073) we added a sensitivity analysis to study the potential impact on the drawn conclusion for the primary outcome. To obtain a non-statistically significant difference between both groups, the time needed for dressing change for patients with missing data would

have been at least 2.8 times longer for the 3 patients in the SecurAcath® group compared to the 10 patients in the StatLock® group. Since this is highly unlikely, we can safely conclude that the obtained finding on the primary outcome is robust with respect to the presence of missing data. Additional information on sensitivity analysis may be found in the supplementary files and is illustrated in Supplementary Figure 2 Sensitivity Analysis. Third, we also missed data at removal, especially in the StatLock® group, because these PICCs could be easily removed by staff nurses while in the SecurAcath® group, nurses of the vascular access team involved in the study removed most of the PICCs. However, we assume limited bias in the usability results because StatLock® is not associated with difficulties at removal. We observed higher pain scores at removal within the SecurAcath® group. A possible explanation could be that in this group not all devices were removed by the experienced APN from the vascular access team, as intended. However, in a post-hoc analysis we found no difference in pain scores as a function of the experience of the clinician within the SecurAcath® group.

Finally, we did not perform a full economic assessment of the use of both devices. Nevertheless, the reduced needed nursing time for dressing change with StatLock® should be taken into account in further financial evaluations. Further research should focus on strategies to reduce pain associated with SecurAcath® and also with TSM dressing's removal. Additionally, the ease of SecurAcath® removal after a long dwell time should be further investigated because in our study, the follow-up time was limited to 180 days.

SecurAcath® is a valuable and safe alternative for StatLock®. However, knowledge and training for precise placement, for smooth handling during dressing change and for a correct removal of the device, are critical.

Conclusion

We compared 2 devices for PICC securement, namely StatLock® which has to be changed weekly, and SecurAcath® which remains in place for the complete PICC dwell time. We found a statistically significant reduced time for the dressing change. In the development of new

technologies, the potential of reducing nursing procedural time is an important factor given the nursing shortage.

Acknowledgement

We want to thank Dr. W.E. Peetermans for reviewing CRBSI in our study patients.

Legends

Figure 1 PICC secured with StatLock®

Figure 2 PICC secured with SecurAcath®

Figure 3 Patient Flow

Supplementary files

Supplementary Figure 1 Boxplot time measurements

Link text: A boxplot shows the distribution of the time measurements in the SecurAcath® versus Statlock® group (Supplementary Figure 1 Boxplot time measurements in supplementary files).

Supplementary Figure 2 Sensitivity Analysis

Link text: Additional information on sensitivity analysis may be found in the supplementary files and is illustrated in Supplementary Figure 2 Sensitivity Analysis.

Contributorship statement

Hereby I confirm that all authors meet the criteria for authorship. They have approved the final article and that all those entitled to authorship are listed as authors. Please find more details for each author below.

G. A. Goossens: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

N. Grumiaux: contributions to conception and design, literature search, acquisition of data, data interpretation, writing, final approval of the version to be published.

C. Janssens: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

M. Jérôme : contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published.

S. Fieuws: contributions to conception and design, data analysis and interpretation, writing, final approval of the version to be published.

P. Moons: contributions to conception and design, data interpretation, writing, final approval of the version to be published.

M. Stas: contributions to data interpretation, writing, final approval of the version to be published.

G. Maleux: contributions to conception and design, acquisition of data, data interpretation, writing, final approval of the version to be published

Competing interests

All authors declared no conflicts of interest for this study.

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Data sharing statement

All available data can be obtained from the corresponding author.

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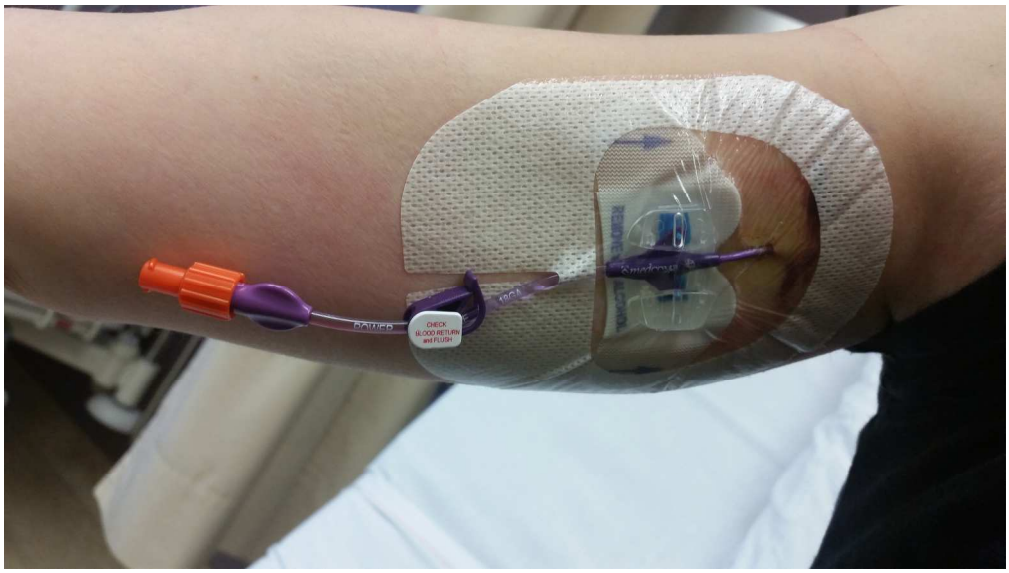


Figure 1 PICC with StatLock®

338x190mm (300 x 300 DPI)

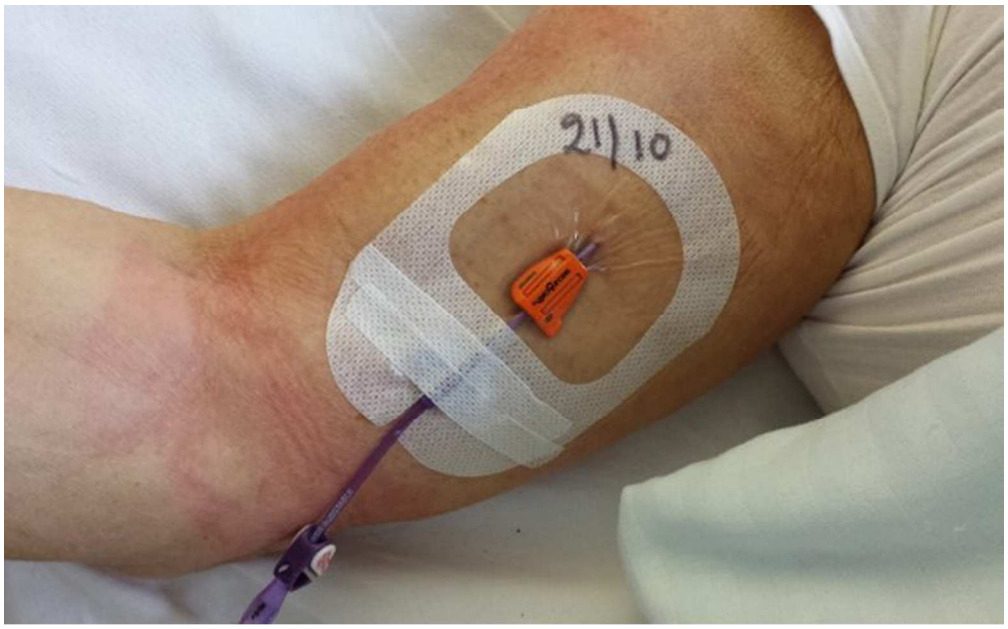


Figure 2 PICC with SecurAcath®

101x62mm (300 x 300 DPI)

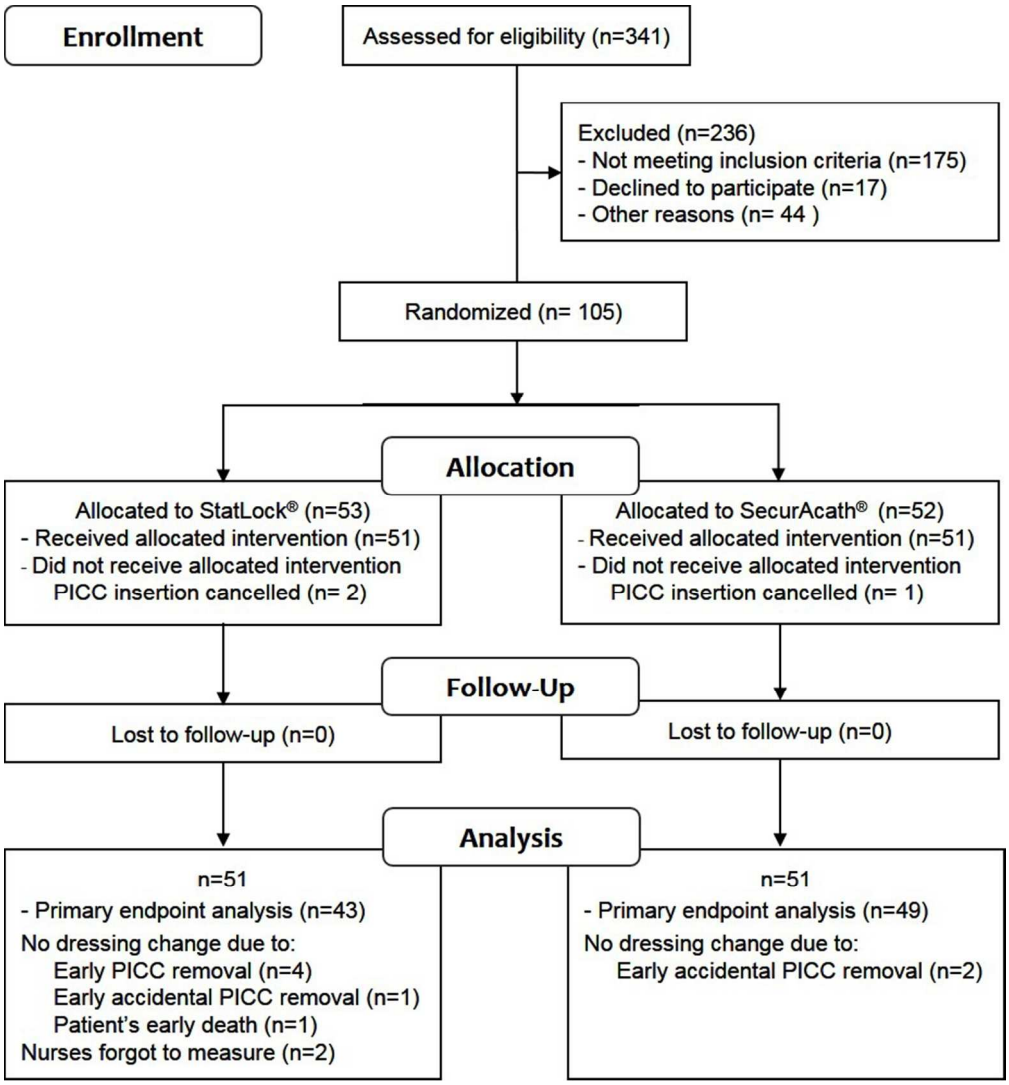
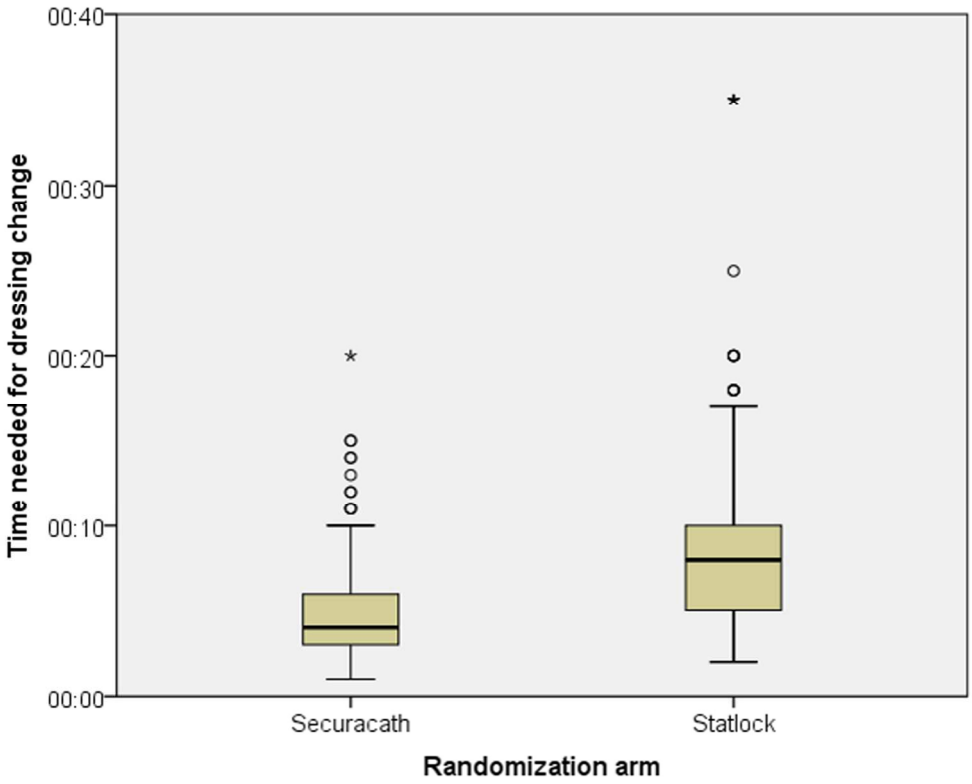


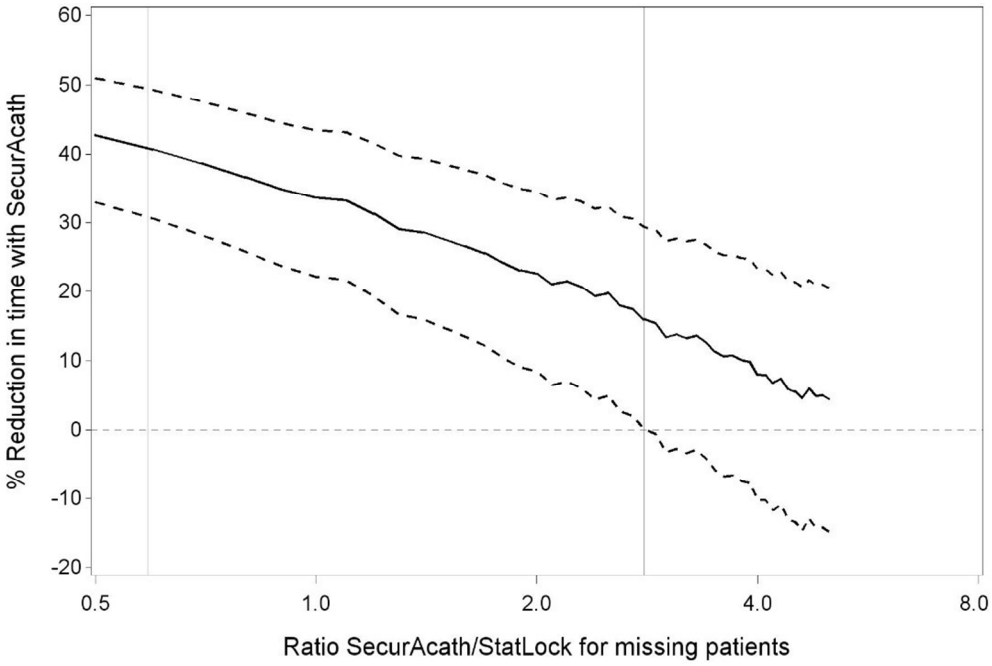
Figure 3 Patient flow

77x83mm (300 x 300 DPI)



Supplementary Figure 1 Boxplot time measurements

166x133mm (300 x 300 DPI)



Supplementary Figure 2 Sensitivity Analysis

92x61mm (300 x 300 DPI)

Supplementary information on Sensitivity analysis

Various scenarios were considered for the randomized patients without any measured time needed for dressing change (3 patients in SecurAcath® and 10 patients in Statlock® group). We repeated the analysis assuming four dressing changes per patient. Data were simulated with parameters obtained from the linear mixed model on the observed log-transformed data. For the fixed effect (i.e. the difference between both groups) various settings were explored. Specific interest was in the worst case scenarios, i.e. scenarios where the time needed for dressing change was longer in the SecurAcath® group, as opposed to the observed data. Within each considered scenario, data were simulated for the patients with missing data and the analysis was performed on the total dataset (105 patients). For each scenario, this was repeated 100 times and the mean (backtransformed from the log-scale) % reduction in time with SecurAcath® and its 95% confidence interval was calculated.

Caption to Figure 5: Sensitivity analysis. Mean (backtransformed from the log-scale) % reduction in time with SecurAcath® and its 95% confidence interval obtained for various scenarios for the ratio SecurAcath®/StatLock® within the group of missing patients. The left solid vertical line refers to the observed ratio (ratio=0.59, i.e. 41% reduction). The right solid line, the ratio which needs to be assumed for the patients with missing data in order to obtain a non-significant difference between both groups.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NAP
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NAP
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NAP
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NAP
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NAP
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NAP
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-11 figure 3 flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	9-11
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NAP
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	11 Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12-19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	12-19
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NAP
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NAP
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	21-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	21-22
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	Local EC
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.